



The Impact of Orthodontic Treatment on Eating Related Quality of Life on different cultures and different age groups (United Kingdom and Kurdistan populations)

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Abstract

Orthodontic treatment is a lengthy procedure that is likely to introduce changes to the patient's Oral Health Related Quality of Life (OHRQoL) and affect some daily activities. Eating is one such activity, however our knowledge of these impacts is limited. In addition there are no existing patient reported outcome measures to assess the effect of orthodontic treatment on eating related quality of life (ERQoL). The aim of this study was to explore ERQoL of orthodontic patients by conducting a qualitative study and developing and validating an ERQoL specific measure. This will expand our existing knowledge of ERQoL and form the foundation of dietary instructions provided before and during orthodontic treatment.

Items for the ERQoL measure were generated from a previous UK based qualitative study conducted at Newcastle University with child orthodontic patients aged 11-14 years old. The data was re-analysed for the current study and the analytical framework (index) used as the information source for question generation. Initially 45 questions were generated and the research team undertook question reduction and categorised the questions into themed domains. In the UK, 12 orthodontists assisted with content analysis to determine the relevance and clarity of the questions according to their own clinical experience and 15 orthodontic patients aged 11-16 years evaluated the measure in the face validity stage. The questionnaire was modified following each of these stages. Finally, 30 British child orthodontic patients answered the questionnaire twice, two weeks apart to determine reliability of the questionnaire. Internal consistency was examined using alpha correlation giving a range of 0.5- 0.84 at a domain level. Test re-test reliability (using intra class correlation coefficient, paired t-test and Wilcoxon rank test) was used to determine the stability and reproducibility of the questionnaire. According to these tests most of the participants gave consistent answers 2 weeks apart. Two questions (adaptation to the orthodontic treatment and swallowing difficulty) did demonstrate statistically significant differences at the two time intervals but were retained due to their perceived importance and relevance to orthodontic treatment. This relevance was confirmed by findings from the UK and Kurdistan qualitative studies.

The final questionnaire was composed of 28 questions within 6 domains. 26 questions were quantitative, using a Visual Analog scale (VAS) as a rating scale and 2 questions were qualitative with a free text area for writing the answers. The ERQoL questionnaire was found to be an acceptable and reliable measure to determine ERQoL during orthodontic

treatment in a larger sample in the UK. To expand our existing knowledge about ERQoL of orthodontic patients during the time of the treatment 30 semi-structured interviews and 4 focus groups were conducted with Kurdish children (11-16 years old) and adults (17-25 years old) in Kurdistan of Iraq. The qualitative data was analysed using a framework analysis and different themes and subthemes were identified in relation to the functional, social, emotional and psychological experiences of the patients during their orthodontic treatment. Participants confirmed that ERQoL in orthodontic patients is affected by orthodontic treatment, particularly at the start of the treatment. The most common features described were pain and the physical obstacle of the appliances which leads to functional and social limitations. This treatment also introduced some eating habit changes as a reaction to the difficulties and affected the enjoyment of eating. Chopping some foods into smaller pieces, reducing eating speed, using smaller mouthfuls and retaining the food for a longer time in the mouth were the most common eating habit changes. Moreover most of the participants had a softer diet and avoided hard and chewy food particularly at the start of the treatment. Most of these difficulties were found in both adult and child age groups. Additionally most of the difficulties especially the functional problems were found to be similar between both British and Kurdish cultures.

The quantitative and qualitative findings of this research suggests consistency in eating related difficulties during orthodontic treatment across different ages and cultures. The ERQoL questionnaire may therefore be suitable for use in a wide range of contexts.

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1 Chapter One: Introduction

Orthodontic treatment is a common dental treatment undertaken in children and adults. In the UK approximately one third of children need orthodontic treatment. The Child Dental Health Survey in 2015 estimated that approximately 44% of 12 year old children wanted some kind of orthodontic treatment, and 33% required complex orthodontic treatment (Steele *et al.*, 2015). Furthermore, the same survey indicated that 14% of 12 year olds and 36% of 15 year old children had an orthodontic appliance (Tsakos *et al.*, 2015). In Kurdistan the orthodontic problem is also quite common and nearly 41% of children aged 13 years old need orthodontic treatment and for 10.3% of them the treatment is deemed essential because of a handicapping malocclusion (Al Huwaizi and Ali Rasheed, 2009).

Orthodontic treatment can be delivered using different kinds of appliances according to the age of the patient and type of the tooth movements desired. The most common orthodontic treatment is fixed appliances (Chestnutt *et al.*, 2006). There are also other kind of orthodontic treatments which mostly depend on age and the type of orthodontic problem. For example removable appliances, myo-fuctional appliances and headgear.

Eating is one of those daily activities that is affected by orthodontic treatment and until now basic knowledge exists and limited investigation has been performed about the impact of orthodontic appliances on eating. ERQoL of orthodontic patients is a term used to evaluate eating related outcomes after the insertion of orthodontic appliances and throughout the time of the treatment. Therefore, it is necessary to investigate patients' perceptions and experiences qualitatively as an initial source of information to inform the development of an instrument to measure ERQoL of patients during orthodontic treatment.

Patient-centred measures have been used extensively in the medical and dental fields and a variety of research has been performed focusing on the patient's perception rather than the traditional biomedical quantitative evaluation. Patient-centred models consider the patients' perspective regarding their functional, emotional and social experience alongside their perceived impairment whilst exploring patient satisfaction and the need for conventional treatment or intervention of a disease.

For the clinicians and health policy makers it is important to know how orthodontic patients accept the treatment and how they will cope with the problems and side effects. In the literature, it is well known that orthodontic treatment will bring some discomfort such as pain in the dentition due to force and pressure from tooth movements and discomfort in peri-oral muscles and soft tissues. These lead to functional limitations and a potential negative impact on Quality of Life (QoL) or

Health Related Quality of Life (HRQoL). Therefore, it is important to further explore the problem and investigate how these limitations may affect patients eating and dietary intake and explore possible solutions to these difficulties which could be offered to patients in the form of instructions. Development of a tool to determine ERQoL during treatment will facilitate further research and allow deeper exploration of eating related treatment outcomes.

A qualitative study was also performed in Kurdistan of Iraq on children (11-16 years old) and adults (17-25 years old) to explore more basic knowledge about eating related difficulties with orthodontic appliances in a different culture. A previous qualitative study on the impact of orthodontic treatment on ERQoL in UK children was used as the initial source for question generation whilst developing the instrument to measure ERQoL. A qualitative assessment of both content validity, with orthodontists and face validity, with child orthodontic patients, was conducted to evaluate the questionnaire alongside quantitative investigation of questionnaire findings. The aim was to preserve the notion of patient-centeredness during the development of the questionnaire by reflecting the qualitative findings from both the UK and Kurdistan studies in the developed questionnaire, particularly during the quantitative testing procedure.

Therefore, the structure of the thesis aims to be as simple as possible with chapters divided in such a way that the link between the two studies (qualitative and questionnaire development) can be perceived throughout the thesis. Chapter Two is dedicated to a wide review of literature regarding qualitative research, questionnaire development and the relationship between orthodontic treatment and malocclusion with QoL. Chapter Three presents the research question, aims and objectives. In the two successive chapters each study is presented and then the outcomes of both studies combined together in the general discussion chapter.

2 Chapter Two: Review of Literature

2.1 Quality of Life

The term of quality of life (QoL) first appeared in the book “*The Economic welfare*” by Pigou in 1920 and it was generally described as a person’s sense of well-being (Pigou, 1920). In the medical field, it is becoming more popular after a definition was published for QoL by the World Health Organization. According to the WHO, ‘health’ does not only mean absence of a disease, but also it is “a state of complete physical, mental and social well-being” (WHO, 1995). In the medical literature, it first appeared in a haemodialysis study in 1966 conducted by Retan and Lewis (1966) and from mid-1970s the term appeared in the clinical trial studies, mostly in psychology, rheumatology and oncology fields (Farquhar, 1995). Quality of life is multidimensional and it is difficult to provide a unique definition for it (Felce and Perry, 1995), and many definitions for health and QoL have been stated. Such definitions usually try to link happiness with satisfaction of life (Fayers and Machin, 2007). Emerson (1985) also defined QoL as an individual satisfaction towards their values and needs in their lifestyle with respect to their ability to actualise these concepts. In other words, it is equality between objective perception and an individual’s goals and aspirations (Andrews and Withey, 1976).

QoL is sometimes confusing because of the complexity, adaptability, and subjectivity of health and well-being. Moreover, each person places a special meaning on QoL and this may be subject to change over time (Hunt, 1997). It is not uncommon to see people with serious and sustained disabilities or chronic disease show excellent QoL and satisfaction. This phenomenon is known as the disability paradox (Locker and Allen, 2007). In addition to that, patient adaptation to a disease increases his health state and may provide a higher value than the individual who imagines having a disease (Menzel *et al.*, 2002). In contrast, the general public and health professionals tend to assume that those with disabilities have low QoL (Albrecht and Devlieger, 1999).

This widened concept of health to include QoL suggests that a biological measure of disease should be accompanied by a measure that can evaluate an individual’s perspective. The inclusion of measures of QoL within the evaluation of clinical research has rapidly increased and it may be incorporated with an assessment of efficacy, cost effectiveness, and net advantage of new treatment programs and interventions. QoL measures were developed to act as clinical indicators for population’s need and care, in other words, they were developed to humanise health care and increase personal confidence (Oliveira and Spiri, 2006).

2.1.1 Health Related Quality of Life

Sometimes there may be confusion regarding the terminology between QoL and health related quality of life’ (HRQoL). The first one is a concept mostly adapted to WHO definitions while the

latter is related to those conditions that can be affected by health care practices (Pal, 1996). Therefore, a health measurement criterion that attempts to encompass the effect of health and disease on QoL is described as health-related quality of life. In health studies, especially in medical and nursing journals the term QoL is often referring to HRQoL. Kaplan and Bush (1982) proposed authors should use the term HRQoL to separate health impact from other factors such as job satisfaction and environmental influences.

HRQoL consists of multiple different domains and each of these domains relates to the specific study's question. For some studies, physical and functional fields are the focus of the study, while for others, psychological and social variables are the primary focus. Bowling (2001) describes it as "optimum levels of physical role (e.g. work, carer, parent, etc.) and social functioning, including relationships and perceptions of health, fitness, life satisfaction and well-being. It should also include some assessment of the patient's level of satisfaction with treatment, outcome and health status and with future prospects".

The three concepts of health status, functional status, and QoL are mostly used to indicate the "health" domain. Health is a term that applies to determine the outcome level of any clinical and non-clinical approach. From this perception, health assessment measures are developed and applied. On the other hand, some aspects of life that have a close relationship with health, cannot be considered as a health status condition, such as living standards and the political environment (Fitzpatrick *et al.*, 1998). In contrast, these concepts mostly deal with social, familial, and behavioural factors that impose their effect on the health status of every individual (Patrick and Bergner, 1990). Moreover, HRQoL is an individual and a dynamic notion because perceptions, roles, relationships and practices in life change and can be worsened by health status (Morris *et al.*, 1986).

Historically, HRQoL measures were developed to indicate what a positive health definition is and how to differentiate between health systems (Bowling, 2001). Furthermore, HRQoL decides which type of assessment is necessary and assesses the outcomes of treatment after an intervention. HRQoL is mostly expressed by individual experiences towards either satisfaction or dissatisfaction that is important for the feeling of well-being (Cunningham and Hunt, 2001). HRQoL generally relates to the measurement of less negative domains of life, including death to the more positive domain of life, which is a role, function and happiness (Patrick and Bergner, 1990), or a quantifiable measure like life expectancy and survival rate (Gift and Atchison, 1995).

2.1.2 QoL and HRQoL Assessment

The main problem facing detailed QoL assessment is the lack of a universal agreement on its definition (Bowling and Brazier, 1995). This issue creates difficulty in comprehensive and

efficient assessment of QoL and in generalisation between QoL studies (Guyatt *et al.*, 1993; Muldoon *et al.*, 1998). However, the evidence to support valid and reliable QoL measures has increased (McDowell, 2006). In addition to that, many clinical trial studies have indicated the ability of such measures to determine clinically significant changes (Tugwell *et al.*, 2000).

The first QoL assessment tools focused mainly on the medical model of measuring success and QoL of the patients assessed by the clinicians. One of the first instruments utilised for patient's QoL measurement was the Karnofsky performance scale, which was proposed in 1947 for use in the clinical setting (Mor *et al.*, 1984; Schag *et al.*, 1984). This scale and other successive instruments only captured one aspect of QoL, which was functional ability; as a result, these instruments were unable to represent overall patient's well-being (Fayers and Machin, 2007).

Assessing QoL of patients has become an integral part of the health system policy. One of the main justifications for measuring QoL is the difference in patient's responses to the same clinical criteria. The second reason is a difference between the patients and practitioners' perceptions toward the functional ability and well-being (Guyatt *et al.*, 1993). However, the aim of clinical intervention is to enhance the QoL and well-being by relieving clinical symptoms and increasing the survival rate (Cunningham and Hunt, 2001).

QoL is multi-factorial and related to the patient's feeling and health professionals cannot exactly measure QoL of patients. Furthermore, opinions and views of doctors and health professionals may vary, so it is difficult to find out a clear-cut measure for the assessment of QoL. Lastly, it has been suggested that QoL measurements should be directly derived from the patients themselves and not their health care practitioners because it is difficult to determine exactly what the patients feels. In other words it must be patient or person-centred and incorporate those aspects of daily life that may be compromised by the disorder (Locker and Allen, 2007).

There are some different situations in which HRQoL measures could be used for assessing treatment needs and outcomes. Such as, regular patient monitoring, clinical trials, improving the relationship between patients and healthcare providers, comparing different responses of patients in terms of health gain and analysing better choices for health care organisation in terms of services and financing (Cunningham and Hunt, 2001).

2.1.3 Who is the Best Candidate to Measure the Quality of Life?

In measuring QoL, it is essential to affirm who is the right person to report this; clinician, patient or parent/ caregiver in case of children. Clinicians are experts in the field and have lots of background information and details about the problem. However, the patients are the persons who are suffering from the condition or undergoing the treatment. It has been demonstrated that health care provider's tend to report on the obvious symptoms and generally psychological aspects tend

to be underestimated (Fayers and Machin, 2007). Parents or caregivers can also report on HRQoL of child aged patients when communication is problematic, but the validity of such reports is questionable (Theunissen *et al.*, 1998).

In a study conducted by Jachuck *et al.* (1982) on controlled hypertensive individuals, the patients, physicians and relatives rated the improvement level. After completing a questionnaire the results showed that all the physicians in the study were satisfied with the level of improvement. In contrast, nearly half of the patients indicated there was no change and 8% reported that the condition had deteriorated. Because of the presence of many subjective feelings, clinicians or health workers are unable to assess all of the patient's perceptions and therefore cannot determine the QoL of the patient adequately (Slevin *et al.*, 1988)

However, in some circumstances it may be appropriate to use another person to answer the question as a proxy (Guyatt *et al.*, 1993), for example, children can rely on their parents during answering of the questions (Eiser and Morse, 2001). For child-aged patients it is important to decide who is going to report their HRQoL. Until recently QoL of children was mostly assessed by their parents or caregivers rather than children themselves, due to concern regarding their cognitive level and communication abilities to interpret the questions and provide understandable information. This issue questions the validity and reliability of such reports (Theunissen *et al.*, 1998). The observable side of QoL which includes mostly the functional part is more obvious for the parent to describe compared to the non-observable sides of QoL, including emotional and social aspects. In other words the parents reporting accuracy mainly depends on the domains of QoL being questioned (Eiser and Morse, 2001).

Jokovic *et al.* (2003) investigated the level of agreement between reports of mothers, as proxies, and children. Although they determined a good level of agreement, they still suggested obtaining both views to represent child HRQoL completely. In contrast, Wilson-Genderson *et al.* (2007) reported a poor to moderate agreement between children and their caregiver. They showed that a group of child orthodontic patients reported lower QoL than their caregivers. In general, older children possess an adequate level of understanding, and can memorise and retrieve past events and experiences and this is directly proportional to their age (Gathercole, 1998; Pickering *et al.*, 1998). In addition, older children are able to deal with self-reported questionnaires because of the maturity of their language skill with regards to independent reading and comprehension (Roman *et al.*, 2009).

2.1.4 Types of Instrument for Measuring HRQoL

Measurement of health and HRQoL is an important step in the understanding and treatment of disease. Health is multidimensional and needs careful measurement to visualise the spectrum of

potential problems. The outcomes of the measurements can be used in optimising prevention or treatment approaches and the future health and functional statuses can be projected (Gift and Atchison, 1995). However, one of the important elements in any type of health instrument in evaluating the treatment intervention, is its sensitivity to change, responsiveness and longitudinal validity (Agou *et al.*, 2008a).

Two main types of instrument exist - generic instruments and specific instruments. Generic instruments provide a summary of overall HRQoL in a single health profile while condition specific instruments are derived for a particular disease, problem, condition and specific population to assess patient's perception (Cunningham and Hunt, 2001). Both measures are able to determine clinically significant changes in patient's daily life and comparison of disease across different situations (Tugwell *et al.*, 2000).

a. Generic instruments

Generic instruments can be divided into health profiles and utility measures (Guyatt *et al.*, 1993). Health profiles can measure the important aspect of QoL in health, regardless of the underlying condition. Such measures usually contain different health domains in a multiple scale format. One widely used such measure is Short Form-36 (SF-36) Health Survey Questionnaire (Ware Jr and Sherbourne, 1992). Whereas utility measures relate to decision-making and the economy which is useful for health care providers to allocate treatment resources. This type of instrument cannot measure HRQoL whilst it is able to identify an improvement in a particular treatment or intervention after comparison with other available interventions (Bowling, 2001). Euroqol is an example of a utility measure which is not a disease related measure and is used in evaluation of HRQoL economically (Brooks and Group, 1996). This measure has also been used to evaluate the health estimation based on data from an oral health measure (Brennan and Spencer, 2013).

Generic measurements are designed to be applied to different types of diseases with different severities; they also can be applied on a variety of medical interventions in different environments and cultural backgrounds. Furthermore, generic measures can capture and summarise the concept of QoL and health across different diseases, populations and patients (Patrick and Deyo, 1989). Therefore, with different populations, the generic instrument can compare the relative impact of various health care programs across a broad spectrum (Guyatt *et al.*, 1993).

In contrast, due to lack of sensitivity to the particular disease, these instruments fail to detect patients' special concerns and cannot differentiate between the consequences of different treatment approaches within clinical trials (Fayers and Machin, 2007). Additionally, a generic measure may not suit assessment of orthodontics as patients are generally in good physical health and therefore may consider that some of the questions are irrelevant (Cunningham and Hunt, 2001).

b. Specific instruments

Approaches using specific instruments mostly focus on a particular area or condition of interest to measure QoL in order to increase the responsiveness of the instrument to the aspect being studied. It is called specific because it deals with one aspect, such as a specific disease, specific population, certain function or particular problem (Guyatt *et al.*, 1993). These measurements are supposed to determine a particular condition or diagnoses in a group or specific patients, they are more sensitive to small, but clinically important changes over time in a particular population. These changes are of concern for both patients and clinicians and are related to a known efficacy psychological measure or intervention (Patrick and Deyo, 1989).

In general, the specific instruments need to have high content validity in order to be relevant to the specific situation of the under investigated population, in contrast to the generic measures which are reported to have low content validity (Patrick and Deyo, 1989). As a result, the sensitivity of specific instruments is usually higher than generic instruments and therefore more relevant to determine the oral health related QoL (Cunningham and Hunt, 2001).

2.1.5 Types of Specific instrument

a. Domain specific instrument

Some specific instrument deal with well-defined dimensions of QoL like social or psychological aspects. The Beck Depression Inventory (Beck *et al.*, 1961) can be regarded as an example of such type of measure. This is a psychometric test for measuring the severity of depression which also categorises under dimension specific measures. The McGill Pain Questionnaire is also an example of such a measure (Melzack, 1975). These types of measures have the ability to provide a more detailed assessment, while being mostly related to the diagnostic assessment rather than the outcome measure (Fitzpatrick *et al.*, 1998).

b. Disease specific instrument

Disease specific measures can provide patients' perceptions in regards to a specific disease such as the Chronic Respiratory Disease Questionnaire, which is used specifically for patients with lung diseases (Guyatt *et al.*, 1987). The content relevancy of such measures is high because the items are specifically developed to assess the specific health problem (Guyatt *et al.*, 1989) and more sensitive to changes that occur over time (Patrick and Deyo, 1989). One of the obvious disadvantages of such measures is the inability to apply them on healthy populations, particularly when comparison with a healthy control group is necessary (Fitzpatrick *et al.*, 1998).

c. Site-Specific Instrument

This type of instrument is usually related to a specific part of the body or a particular medical intervention. These instruments are unable to explore the overall QoL and because of their narrow perspective are unlikely to detect complications of a treatment (Fitzpatrick *et al.*, 1998).

2.1.6 Oral Health Related Quality of Life (OHRQoL)

It is difficult to define the exact relationship between quality of life, general health and oral health, but oral health is regarded as an integral part of human general health and it is likely to contribute to the overall HRQoL determination (Gift and Atchison, 1995). A systemic review by Naito *et al.* (2006) reported that, due to the lack of evidence to illustrate the relationship between oral health and HRQoL, it is difficult to assess this impact using generic HRQoL instruments. This systemic review showed that some studies using a generic HRQoL instrument were unable to demonstrate links between multiple tooth loss / caries condition and HRQoL (Allen *et al.*, 1999; Broder *et al.*, 2000).

Oral diseases are a worldwide problem and have a higher frequency than other medical conditions, but are rarely life threatening. Therefore, less attention has been paid to oral health by health care providers as well as health policy makers, often treating oral diseases and problems as a separate part of body from general health (Gift and Atchison, 1995; Cunningham and Hunt, 2001). During the 1980s the term OHRQoL appeared in the literature exploring the concept that oral health includes functional and psychosocial well-being, which is wider than the concept of oral diseases (Locker, 1996). Whilst good periodontal condition or caries free dentitions may demonstrate optimum oral health it does not explain the multi-dimensional subjective perception of individuals own oral health and the impact of that on daily life (Gilbert *et al.*, 1998). Therefore, to define optimum oral health the focus should not only be on the oral cavity but also explore its link with other medical conditions and overall wellbeing (Locker, 1997).

Functional and psychosocial outcomes of oral diseases can be assessed by OHRQoL measures. It is generally accepted that oral health outcomes act as a clinical indicator for evaluating individual and community oral health and can be used for planning health programs and interventions (Allen, 2003; Jokovic *et al.*, 2004). Three different approaches can be used to determine OHRQoL; firstly the outcomes of oral cavity itself; secondly the impact of the oral health condition on the general health of the body; and finally the impact of systemic diseases on the oral health condition (Gift and Atchison, 1995).

The relationships between oral health and QoL should be clearly explored, where possible defined to allow health policy makers to offer better and systematic approaches towards the improvement of the QoL of individuals. Cohen and Jago (1976) clearly stated that the main importance and greatest roles of dentistry are improvement of an individual's QoL through the treatment and

prevention of oral and dental problems. OHRQoL measures have been developed for dental practice to uncover the impact of psychological, social and physical well-being on patient's perception and oral health satisfaction (Cunningham and Hunt, 2001).

2.1.7 Conceptual Models in OHRQoL

Several conceptual models exist which try to identify different elements of subjective wellbeing. In other words, conceptual models in health studies aim to find the relationship between the clinical and non-clinical variables with HRQoL.

The Wilson and Cleary model is one of the well-known models of health (Bakas *et al.*, 2012) which can also be implemented for dental research (Williams *et al.*, 1998; Baker *et al.*, 2007). This model encircles health, disease, and QoL and determines the causal relationship between these factors, whilst focusing on personal and environmental characteristics. From this model, the focus of previous research can be clarified and defined. Most of the patient-centred outcome studies have focused on functional and symptom status, general health perception and overall quality of life (Wilson and Cleary, 1995). Whereas individual and environmental characteristics have been given less consideration (Ferrans *et al.*, 2005). On the other hand it is important to know that each of the model's components may be independent and the element does not necessarily lead to the next level (Locker, 1996). Wilson and Cleary (1995) indicated that objective circumstance could not fully determine generalised life satisfaction measures. That is why in some patients considerable dental irregularities do not affect overall QoL whereas for others even a lesser degree of malocclusion can produce significant change in life satisfaction. Therefore, individual and environmental factors will demarcate some of these variations in perception.

International Classification of Functioning, Disability and Health (ICIDH) is another conceptual model provided by WHO (1980) (Figure 2.1). This model tries to indicate the effect of functional limitation, pain and discomfort on the handicapping state of the individual. Handicap here has a holistic meaning which includes physical, psychological and social handicaps. ICIDH mostly emphasises the consequence of the disease or disorders i.e. disabilities through anatomical, psychological and physical impairment. Disabilities or impairment produce impact on the individual by limiting the personal fulfilment which is the handicap at the end result (WHO, 1980). This model is unable to be used as an assessment tool for research, but it can be regarded as a foundation to explore patients' experiences of the disease.

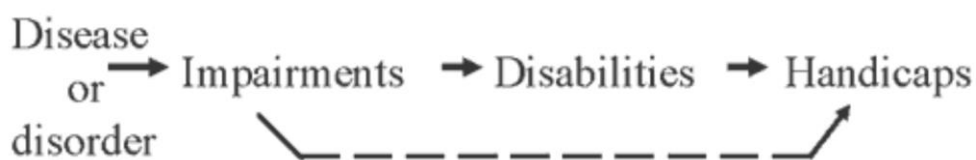
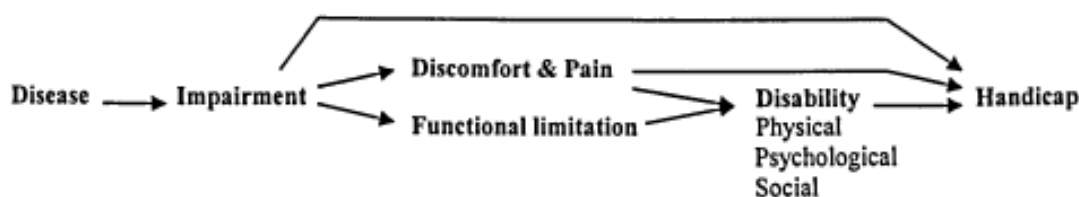


Figure 2.1 International Classification of Functioning, Disability and Health (ICIDH) (WHO, 1980).

Most of the OHRQoL measures are in some ways extracted from the WHO frameworks of International Classification of Impairments, Disabilities and Handicaps (ICIDH) (Badley, 1987). Locker (1988) modified this framework to be applicable for dental practice (Figure 2.2). According to this concept any diseases affecting the oral and facial structures produce five

Figure 2.2 Locker Conceptual Model (Locker, 1988).



sequential outcomes in which the handicapping is a final stage. Locker clarified that diseases leading to impairment which either cause discomfort or pain (physical or psychological) or functional limitation (such as difficulties in eating due to tooth loss) should be considered. Pain or functional limitation can directly end up as a handicapping condition. Whereas, functional limitation may cause physical and psycho-social disabilities which result in a handicapping condition through issues such as social isolation and an unsatisfactory diet. Therefore, with the Locker model the multi-dimensional concept of oral health can be defined in a wider context considering not only biological and physical effects but also psychosocial interactions.

2.1.8 Reflection of the Conceptual Models on OHRQoL

Poor oral health conditions will negatively affect OHRQoL and therefore clinical determinants like gingival and periodontal diseases, malocclusion, dental caries and cleft lip and palate have been studied to establish their relationship to the well-being of affected patients. Gherunpong *et al.* (2004b) explained that bleeding and swollen gums reduced the OHRQoL of 20% of Thai children and the oral impact was mainly associated with eating and smiling. The low level of dental caries also produced a considerable positive effect on OHRQoL of rural Ugandan children (Robinson *et al.*, 2005). Several studies have explored the impacts of children's malocclusion on OHRQoL (Foster Page *et al.*, 2005; O'Brien *et al.*, 2006; Johal *et al.*, 2007; O'Brien *et al.*, 2007;

Bernabe *et al.*, 2009). Johal *et al.* (2007) have indicated that spacing and increased overjet produce a negative impact on the QoL of both families and the children. This is supported by the observation that children with severe malocclusion had more oral impact than others with no or slight degree of malocclusion (Bernabe *et al.*, 2009). In the same way Australian children with less acceptable occlusal traits reported poorer OHRQoL (Do and Spencer, 2008). Cleft lip and palate conditions are considered to have a larger impact on the patient's OHRQoL. Because of the impact of this condition on facial appearance, it has more potential to adversely affect QoL and well-being than most other dental problems due to its obvious clinical effect which may continue throughout life. On the other hand, Locker *et al.* (2005) concluded that children with chronic orofacial conditions are more likely to adapt to their situation and only few differences in their HRQoL can be perceived in comparison with other children with common dental problems. In fact, patients with chronic orofacial conditions face many challenges in their daily life, but many are still well adjusted and cope with the conditions, this is called "Disability Paradox" which seems to be against all odds (Albrecht and Devlieger, 1999).

Non clinical determinants like individual, social, psychological and environmental factors also affect OHRQoL. The relationship between these factors and OHRQoL are not well established in dental research and in the Wilson and Cleary model only a weak relationship can be noticed. Although some studies found a weak relationship between the clinical indicators and OHRQoL (Locker *et al.*, 2005; Daly *et al.*, 2010), the non-clinical indicators may be regarded as the cause of reducing the interaction between the clinical indicator and OHRQoL (Baker *et al.*, 2007).

Examples of individual factors which might influence OHRQoL are age and gender. Few studies have evaluated the influence of these personal determinants on the OHRQoL (Onyeaso, 2003; Klages *et al.*, 2004; Marques *et al.*, 2006). Females are more concerned about their dental appearance than boys are and considered their attractiveness below the average level (Shaw, 1981a). Moreover, teenage females between 13- 16 years old express more concern about their dental appearance, particularly crowding of the dentition, than girls of a younger age (Gosney, 1986). In contrast O'Malley and Bachman (1983a) indicated that whilst age itself is not a direct factor, age related variables are the main determinants of QoL outcomes.

2.1.9 Selecting the OHRQoL Measure

Traditionally, oral disease is assessed using clinical parameters such as DMFT (decayed, missing, filled teeth), IOTN (Index of Orthodontic Treatment Need) and periodontal indices. However, these are limited because they only show a part of the whole impact of oral problems on daily performance (Allen *et al.*, 1999). Due to the impact of the oral disease on daily activities and well-being it is essential to establish an instrument to measure the overall impact of oral health on daily

life. Instruments to measure OHRQoL vary from single dimensional to multi-dimensional instruments. According to Streiner *et al.* (2015) having adequate multiple item observations in an instrument will reduce the random errors as a result of interaction between the items and cancellation of errors. Consequently, they can measure the degree of disturbance of an oral condition that is affecting an individual's QoL or measure the impact of oral problems on the social life of the individual (Reisine *et al.*, 1989).

In dental research, the Locker model has been applied to establish different types of OHRQoL measures, including the Oral Impacts of Daily Performance (OIDP), Oral Health Impact Profile (OHIP) and Child Perception Questionnaire (CPQ). Other measures have also been used in orthodontics such as Psychosocial Impact of Dental Aesthetics Questionnaire (PIDAQ) (Klages *et al.*, 2006) and an instrument for determining the QoL of orthodontic and orthognathic patients, the Orthognathic Quality of Life Questionnaire (OQOL) (Cunningham *et al.*, 2002).

Due to continuous changes in the oral health, QoL perception is vulnerable to change as well, which may lead to a shift in the response of QoL measures. These changes can happen due to the effect of treatment and relatively because of the recursive nature of the condition in accordance with the daily personal environment (Gregory *et al.*, 2005). In addition to that, in children, growth, cognitive ability and psychosocial changes will increase measurement difficulties (Allison *et al.*, 1997; McGrath *et al.*, 2004).

The first step for an accurate OHRQoL selection is specification of the purpose of using the instrument. The second step is the identification of a measure, which is appropriate for the intended study. Therefore, a measure that is suitable for cross-sectional study may not be suitable in a longitudinal study (Skaret *et al.*, 2004).

Moreover, using a patient-centred measure is important to capture the experiences of the patient in healthcare settings. In orthodontic QoL studies a specific OHRQoL measure is usually required to capture small but clinically important changes in the patient's health (de Oliveira and Sheiham, 2004).

The Child Perceptions Questionnaire 11-14 (CPQ11-14) is commonly used for determining OHRQoL in children and adolescents aged 11-14 year old (Jokovic *et al.*, 2002; Locker *et al.*, 2007; Agou *et al.*, 2008b; Goursand *et al.*, 2008). It measures oral symptoms, functional limitations, emotional and social well-being. It consists of 37 items, but for ease of use in the clinical setting, it has been shortened to 16 and 8 items for clinical and epidemiological surveys respectively (Jokovic *et al.*, 2006). This instrument was developed by deriving the items from the literature as an initial tool for the item generation and then testing it with experts, parents and children. Content validity and face validity were the chosen methods for the testing procedure.

Jokovic *et al.* (2002) claimed that children possess homogeneity in the role and cognitive abilities and found that the instrument can be used universally with 11-14 year olds for assessing OHRQoL. Despite using children in the content validity phase for selecting the initial items, professional and adult perceptions predominated in most of the well-known instruments. However, several studies have used this instrument to assess OHRQoL of patients with malocclusion and in different stages of orthodontic treatment or to compare QoL before and after an intervention or treatments. (Foster Page *et al.*, 2005; O'Brien *et al.*, 2006; Zhang *et al.*, 2008)

In other orthodontic studies, the psychological, physical and social effects of the orthodontic treatment on a patient have been investigated (de Oliveira and Sheiham, 2004; Zhang *et al.*, 2007; Chen *et al.*, 2011; Johal *et al.*, 2013). One of the points that can be detected in most of these studies is deterioration of OHRQoL during orthodontic treatment when compared with pre or post treatment measurements. Zhang *et al.* (2008) found that specific aspects of OHRQoL such as symptoms of intra-oral complications and functional limitations worsen significantly for about 6 months after insertion of the appliances. The lack of some essential measures for developing an OHRQoL instrument, such as content and face validity, in most of these studies may contribute to emerging inaccurate results (Klages *et al.*, 2005; Mandall *et al.*, 2006; Feldmann *et al.*, 2007; Marshman *et al.*, 2010). Furthermore, most of these studies utilised a generic measure rather than a specific one for patients with malocclusion, which in turn may lead to the production of some irrelevant items (O'Brien *et al.*, 2007).

For capturing patient perceptions about the impact of the oral problems on HRQoL it is crucial to conduct a patient-centred assessment. Marshman *et al.* (2010) conducted assessment of face-validity and content-validity with younger children with orthodontic problems to express their concerns about the Child Perceptions Questionnaire (CPQ ISF-16). The children were asked about the wording, response format and relevancy of the questions to their experiences. One to-one structured interviews were conducted by Bernabé *et al.* (2008c) with the orthodontic patient to assess the validity of (OIDP) in patients who had worn orthodontic appliances in the last six months and showed at least one impact on their daily life. Furthermore, in another study, Ryan *et al.* (2009b) interviewed patients and clinicians qualitatively about their mental health and consultation with professionals in that area before starting orthognathic therapy and a new measure was constructed.

2.1.10 Dietary Intake, Eating Difficulties and ORHQoL

In the literature, limited research on dietary intake and OHRQoL can be found. However, some studies report the impact oral health conditions have on the QoL of the patients. Some general dental studies show that dietary restriction can be avoided by having good oral health to maintain

the proper chewing ability and eating efficiency. Acs *et al.* (1992) examined the effect of early childhood caries (ECC) on the growth and weight of children. They found that progression of ECC might affect growth adversely in comparison with less nursing caries in children. Moreover, similar results were detected in another study on the effect of rampant caries conducted by Ayhan *et al.* (1996).

There is also a positive relationship between the dietary intake of adult patients and oral health status which in turn may affect the general health condition. Consumption of high fibre foods is an important preventive measure to many gastrointestinal disorders (Mann and Cummings, 2009; Elleuch *et al.*, 2011). In the study of Brodeur *et al.* (1993), older edentulous patients were found to be more prone to develop gastrointestinal disorders due to their limited masticatory abilities to consume high fibre food frequently. Marcenes *et al.* (2003) also explained that edentulous patients take some nutrients in lower amounts compared with the dentate patients. Moreover, they indicated that preserving natural functional teeth into old age would play a vital role in having a healthier diet and satisfactory body mass index.

In the orthodontic literature pain is regarded as the main cause of discomfort and impact on OHRQoL during treatment, and patients relate this pain to eating difficulties. The magnitude, prevalence and time course of the pain relating to eating has been reported by many (Sergl *et al.*, 1998; Bartlett *et al.*, 2005; Polat, 2007; Bergius *et al.*, 2008; Rakhshan and Rakhshan, 2015). Scheurer *et al.* (1996) and Bergius *et al.* (2002) reported that the initial days after insertion of the appliance or after the placement of elastic separator the pain intensity reached a peak within 2 days and decrease after 5-7 days from insertion. Dietary intake may deteriorate according to the frequency and magnitude of the pain. On the other hand, Johal *et al.* (2013) reported that during the first 3 months of orthodontic treatment there was no significant detrimental effect on dietary intake or behaviour, BMI and fat percentage.

Whilst many studies have explored the impact of pain during the course of orthodontic treatment on OHRQoL, there are few studies exploring consequence of these impacts on a patient's QoL and particularly on eating.

2.2 The Impact of Malocclusion on QoL

2.2.1 Introduction

Malocclusion is a common oral problem that can be defined as a misalignment of teeth with each other, either in the same arch or between maxillary and mandibular arches and where the degree of irregularity is considered beyond the acceptable level (Proffit, 2007). Malocclusion is not a true disease like other dental or medical conditions, but it is a deviation from the arbitrary norm (O'Brien *et al.*, 2007). Many factors lead to the occurrence of malocclusion. Some of these factors

are hereditary (Ford and Mason, 1943; Mossey, 1999) and others are acquired environmental (Cozza *et al.*, 2005; Peres *et al.*, 2007).

Although malocclusion is not a life-threatening condition, it imposes its effect on an individual's health in terms of social, psychological, and functional problems. A study of orthodontic patients and their parents revealed that both groups believe that aesthetic improvement of irregular dentition and dental arches can be achieved by performing orthodontic treatment (Sayers and Newton, 2007). However, both parents and children expected to have eating, speaking difficulties during the treatment and they had high expectations for having straight teeth and a nice smile. Moreover, they predicted a negative reaction from the public whilst wearing the fixed orthodontic appliances and it was perceived that this would increase the level of embarrassment. In contrast, patients and their parents expected that treating the malocclusion would not improve mastication and speaking (Sayers and Newton, 2007).

The appearance of dental irregularities and malalignment is the main reason for seeking orthodontic treatment. Whether or not patients seek treatment depends on their view towards that abnormality. Some patients with severe irregularities accept the condition while some other patients with mild irregularities are not satisfied with it and seek possible treatment (Shaw, 1981b). It is common to find many adolescents who are dissatisfied with the appearance of their teeth; even though they have a good occlusion and arrangement of dentition. As such, during the diagnosis stage of orthodontic treatment, it is important to consider the psychosocial need of the individual (Anosike *et al.*, 2010). The most recent Child Dental Health survey (2013) in England, Wales and Northern Ireland indicated 20% of 12 years old children and 9% of 15 years old children were assessed to have a clinical orthodontic problem while these patients perceived themselves to have acceptable teeth. On the other hand more than the half of 12 year old and two third of 15 year old orthodontic patients wanted their teeth to be straightened, but clinically were determined not to have orthodontic treatment need (Tsakos *et al.*, 2015).

For child-aged patients, parental concern for treating malocclusion is more frequent than child's concern, so the parents have an important role in motivating the child during this period (Lewit and Virolainen, 1968; Birkeland *et al.*, 1996). However, in the Child health Dental Survey this trend was reversed by which 44% of 12 year old children preferred their teeth to be straightened while only 26% of parents wanted orthodontic treatment for their 12 year old child (Tsakos *et al.*, 2015). The best indicator for the parent to seek orthodontic treatment is the presence of irregularities of the child's teeth. Although the degree of severity of malocclusion is an apparent indicator of the orthodontic problem, the decision for parents and patients to seek treatment is mostly related to the perceived aesthetics of the malocclusion (Tung and Kiyak, 1998).

Each individual has their own opinion towards malocclusion and misaligned teeth which is difficult to assess subjectively (Anosike *et al.*, 2010). Furthermore, the perception of the patient, especially children and the evaluations and concerns of the professional towards the malocclusion are different, (Anosike *et al.*, 2010; Murray *et al.*, 2015). Patient's perceptions can be regarded as a good indicator of whether they will demand treatment how well they will cooperate during the course of the treatment (Shaw, 1981b). Consequently, taking account of the patients view may provide better treatment outcomes, better patient adherence to the treatment plan and greater satisfaction with the results.

2.2.2 Malocclusions Indices and OHRQoL Measures

Malocclusions can be classified quantitatively by indices and several types of indices exist in the orthodontic field such as the Malalignment Index (Van Kirk, 1959), Treatment Priority Index (TPI) (Grainger, 1967), Dental Aesthetic Index (DAI) (Cons *et al.*, 1986), Index of Orthodontic Treatment Need (IOTN) (Brook and Shaw, 1989) and the Peer Assessment Rating (PAR) (Richmond *et al.*, 1992).

The most common indices used for determining the severity and complexity of malocclusions and the level of treatment need are IOTN and DAI due to their proven validity and manageability (Brook and Shaw, 1989; Jenny and Cons, 1996). IOTN can be regarded as the first index, which included socio-psychological indicators for allocating the needs of treatment Baca-Garcia *et al.* (2004). The aesthetic component (AC) of IOTN considered orthodontic patients perception to determine their malocclusion based on 10 photographs. Furthermore Baca-Garcia *et al.* (2004) claimed universality of the DAI index without the need of modifications or changes when applied to different cultures and ethnic populations. These indices are also able to direct financial strategies for the orthodontic care policy makers, introducing a system of rationing of care. The other classification systems like Angle's classification and British Standards Institute classification which are just categorised the malocclusion rather than focusing on the necessity of the treatment. Such kinds of classifications or indices have limited applicability in epidemiological studies.

One of the important questions that should be asked is the ability of these measures to elaborate the real need of patients for orthodontic treatment. The clinical indicators of treatment need can be regarded as a partial indication for the treatment. OHRQoL measures should ideally also be included to optimise the prioritization of treatment for patients and guide the health care policy makers to appropriate allocation of treatment. Prioritising patients' feelings over the clinicians' perceptions is important (Bowling, 2009) and the decision of accepting or rejecting a particular form of malocclusion is influenced by idiosyncratic judgment (O'Brien *et al.*, 2006). As such, the

consideration of the OHRQoL measures with clinical indicators is important because the perceptions of patients and clinicians regarding treatment need may be different.

According to the Child Dental Health survey (2013) 14% of 12 year old and 36% of 15 year old orthodontic patients had had “a brace fitted or adjusted” (Tsakos *et al.*, 2015). Furthermore the 3rd report of the same survey indicated that 37% of 12 year olds and 20 % of 15 year olds had unmet orthodontic treatment need (Steele *et al.*, 2015). In the UK, IOTN is used as an indicator to prioritise the needs of treatment according to the severity and the complexity of the malocclusion. The DAI is used widely to determine the priority of the treatment according to the objective aesthetic needs. Gherunpong *et al.* (2004b) and Gherunpong *et al.* (2006) conducted studies to estimate treatment needs of orthodontic patients in Thailand using both normative treatment need indices and equal measures. The result showed the level of need was decreased when using an ORHQoL measure compared with normative need assessments and this can be regarded as a marked difference between these two approaches. This finding was consistent with other studies that were undertaken alongside other types of dental treatment (Adulyanon, 1996; Srisilapanan *et al.*, 2003). Therefore, to include different elements of the oral health measure, it is important to combine normative treatment need indices with OHRQoL measures to outline the different aspects of oral health.

2.2.3 Physical Effect of Malocclusion

Malocclusion itself does not cause pain, but pain may arise because of:

- Gingival inflammation / periodontal disease due to crowding restricting oral hygiene or a traumatic bite;
- Dental trauma due to prominent / proclined upper incisors;
- Temporomandibular Disorder (TMD) which may be related to aspects of malocclusion.

Malocclusion can affect periodontal and gingival health and patients with normal occlusion have been reported to have better periodontal health than those with malocclusion (Bollen, 2008). Gingival and mucosal trauma may give rise to pain, particularly in patients with an increased overbite for example in severe class II division 2 malocclusions. In such cases, the maxillary incisors may have a direct contact with labial gingiva of the mandibular incisors (or mandibular incisors have direct contact with palatal tissue), which may lead to gingival recession (Geiger, 2001). Patients with class II division 1 malocclusions have proclined maxillary incisors, which are more prone to dental trauma, especially the central incisor (Çelenk *et al.*, 2002; Oliveira *et al.*, 2007; Rodríguez, 2007). Patients with a larger overjet greater than 3mm are more liable to trauma of maxillary incisors than patients who have an overjet of less than 3mm (Nguyen *et al.*, 1999).

Furthermore, patients with an anterior open bite have double the chance of trauma than children with a normal occlusion (Oliveira *et al.*, 2007).

Temporomandibular disorder (TMD) is a collective term that refers to multiple disorders that affect the masticatory muscles and temporomandibular joints. The exact aetiological factors of this disorder still unclear, but malocclusion and trauma are likely predisposing causes (Dimitroulis, 1998). The relationship between malocclusion and TMD is controversial. Several longitudinal studies have suggested that cases with untreated malocclusion over a long period have a greater tendency for TMD. Large overjet in Class II patients, lateral and anterior open bites, posterior cross bite in Class III malocclusion are those cases which have been reported to contribute in the long term to symptoms of TMD (Pahkala and Laine-Alava, 2002; Egermark *et al.*). However, other studies reported weak or no relationships between malocclusion and TMD (John *et al.*, 2002; Gesch *et al.*, 2005). Iodice *et al.* (2013) did not find a possible association between posterior cross-bite and TMD.

2.2.4 Malocclusion and QoL

Malocclusion has been shown to impact on physical, social and psychological well-being of individuals (Bernabé *et al.*, 2008b). The relationship between malocclusion and QoL is complex and it is difficult to define a standard way of clarifying such a relationship. Moreover, there is controversy about the relationship between the impact of malocclusion and QoL (Zhang *et al.*, 2006). A number of studies have been conducted to define the relationship between malocclusion and QoL (Foster Page *et al.*, 2005; O'Brien *et al.*, 2006; Barbosa *et al.*, 2009). In some of those studies no obvious associations have been found between the malocclusion severity and OHRQoL measures such as the Child Perceptions Questionnaire (CPQ) (Barbosa *et al.*, 2009). Other factors such as personal, cultural, and environmental factors might also affect the subject's QoL as well as the malocclusion itself. On the other hand, other studies have showed a link between malocclusion and OHRQoL (Foster Page *et al.*, 2005) and the severity of malocclusion which may increase the OHRQoL deterioration (Ukra *et al.*, 2013). Psychological, emotional and social well-being have been claimed to be the link that can be affected by the presence of malocclusion. The reason behind this, is the fact that most orthodontic patients seek treatment to improve aesthetics (O'Brien *et al.*, 2006). However, the impact on OHRQoL must be more complicated than the limited impact of the appearance of the dentition as severity of malocclusion bears no regular relationship with satisfaction with appearance of teeth (Shaw, 1981b; Clijmans *et al.*, 2015). This shows the complexity behind the standard comparison between malocclusion and QoL.

Most of the studies relating OHRQoL and malocclusion utilise the Child Perceptions Questionnaire (CPQ) as the instrument of choice. This is may be due to the fact that the majority

of orthodontic patients are children and adolescents. For the adult patient, the Oral Impact on Daily Performance (OIDP) has been selected by most of the studies. IOTN was the most frequent Occlusal Index used for determining the severity of the malocclusion (Liu *et al.*, 2009).

Ukra *et al.* (2013) conducted a cross-sectional study on New Zealand adolescents to find out whether malocclusion is associated with OHRQoL. The short-form CPQ11-14 was used for determining OHRQoL and Dental Aesthetic Index (DAI) was used for assessment of malocclusion severity. It showed that severe malocclusion may have a negative impact on OHRQoL. In this study gender difference also was monitored. Females were shown to have a poorer OHRQoL and this may indicate that females pay more attention toward their oral health. However, in a cohort study on Swedish children aged 10-14 years old investigated the impact of malocclusion or orthodontic treatment on OHRQoL, using the short-form CPQ11-14-ISF: 16 and the IOTN-Dental Health Component (IOTN-DHC) for assessment of OHRQoL and malocclusion respectively (Dimberg *et al.*, 2016). In contrast, this study indicated that the OHRQoL of children was not affected by malocclusion and there were no differences between male and female participants. Zhang *et al.* (2006) in a systematic review study, indicated the complexity between these two variables and conflicting results can be observed widely throughout the literature (Locker and Allen, 2007; Shaw *et al.*, 2007; Barbosa *et al.*, 2009; Taylor *et al.*, 2009; Feu *et al.*, 2010; Marshman *et al.*, 2010). These two different outcomes may be due to other factors such as personal, cultural, education and environmental characteristics (Barbosa *et al.*, 2009)

In another systematic review by Liu *et al.* (2009), the majority of studies exploring OHRQoL and malocclusion shown to be cross-sectional because the main aim of these works has been to investigate the direct association between these two variables. In contrast, longitudinal studies can also include the outcome of the treatment and explore in more detail the relation between malocclusion and QoL (Silvola *et al.*, 2012). O'Brien *et al.* (2006) performed a longitudinal study on child patients using CPQ11-14 and IOTN. As with the study of Liu *et al.* (2009), emotional and social well-being were the primary concerns of the children rather than oral symptoms and functional limitations including eating difficulties. Aesthetics was the most common reason for orthodontic treatment which can obviously change the OHRQoL of the patients. Of course the factors such as individual variations, socio-demographics and the general dental and oral health must be taken into consideration (Trulsson *et al.*, 2004). In addition to that, the systematic review of Andiappan *et al.* (2015) concluded that the orthodontic patients QoL can be improved by receiving orthodontic treatment. However, due to the lack of standardisation in study design and reporting the OHRQoL measures score such as OHIP-14, the evidence for claiming the improvement in QoL is still poor.

As previously discussed, psycho-social factors are the most common influences of OHRQoL that encourage patients to seek orthodontic treatment, therefore these two factors will be discussed in more detail.

2.2.5 Psychological and Social Impact of Malocclusion

According to several studies, children with a malocclusion are most likely to face bullying by their peers such as name-calling and teasing (DiBiase and Sandler, 2001). Bullying mostly affects school age children (Boulton and Smith, 1994). Severe malocclusion produces an obvious facial deformity and these in turn produce a given nickname for the children which leads to lowering of their self-esteem and increases their anxiety, depression, and feeling of loneliness (Hawker and Boulton, 2000). It is obvious that these unwanted emotional behaviours may affect the personality of children, and may remain even during their adulthood period.

Appearance and attractiveness of the teeth have a greater role in the psychology of the subjects and malocclusion affects the facial aesthetic and attractiveness. This is mostly associated with the reactions of the surrounding people and perceptions toward the own physical appearance. Additionally, interpersonal relationships may be affected by facial attractiveness and visible dentofacial anomalies may impair this relationship (Shaw, 1981b).

Facial attractiveness affects the judgment and treatment of a person by those around them. Langlois *et al.* (2000) indicated that attractive children are offered judgment that is more positive than non-attractive children, and they have more positive traits. Teachers, surrounding people, and even parents treat the attractive child more warmly; also, the intelligence of the individual may be judged by the attractiveness of the facial appearance (Zebrowitz *et al.*, 2002; Hosoda *et al.*, 2003). Some problems of malocclusion such as incisor crowding and median diastemas have been associated with the judgment of an individual's social class. People that possess these two irregularities were judged to be in a lower social class than those with an ideal occlusion (Kerosuo *et al.*, 1995).

Shaw *et al.* (1985) conducted a study examining the relationship between social attractiveness and dentofacial appearance. The study was based on the judgment of eight hundred young adults using portrait photographs of different incisor arrangement of standardised faces. Visual Analogue Scales were used for the measurement of social characteristics such as popularity, friendliness, social class, and intelligence. The result showed that faces with the normal incisor arrangement were more favourable for most characteristics than those with abnormalities in the arrangement of teeth.

2.2.6 Self-esteem and malocclusion

Self-esteem of the patients is another factor which has been used to predict the outcome of the QoL assessment (Seitz *et al.*, 2009). Many studies have been conducted to find out the relationship between self-esteem, satisfaction and malocclusion; and most of this research is cross-sectional in nature (Bos *et al.*, 2003; Onyeaso, 2003; Clijmans *et al.*, 2015; Romero-Maroto *et al.*, 2015).

Self-esteem is often defined as an “individual’s self-perception of his/her abilities, skills, and overall qualities that guides and/or motivates specific cognitive processes and behaviours” (Juth *et al.*, 2008). The reaction of surrounding people imposes its effect on the individuals (Tung and Kiyak, 1998). People who are satisfied with their facial appearance have higher values of self-esteem (Alice and Johanna, 1997) and it has influence on the decision regarding whether or not to treat the malocclusion (Birkeland *et al.*, 1996). Moreover, most patients believe that malocclusion will affect their facial appearance, and they can make their dentofacial appearance better by performing orthodontic therapy (Shaw, 1981a; Albino, 2000).

Age is also another factor that affects self-esteem and satisfaction with body image and dental appearance; with dissatisfaction increasing as age increases. Gosney (1986) found that females in mid-teenage years (13-16 years old) have more concerns about their dental appearance, especially crowding of the dentition, than the younger age girls. Whereas another study indicated no association between age and dental appearance and reported equal importance for both older and younger adults (Tin-Oo *et al.*, 2011). O'Malley and Bachman (1983b) conducted a study on the relationship between self-esteem and age change and reported that age related variations are the main causes for the development of self-esteem. Therefore, self-esteem increases with age, especially after age 13 and the possible explanation for this is the “increases in physical size, in access to adult roles, and in responsibilities and privileges” (O'Malley and Bachman, 1983b).

2.2.7 Impact of Malocclusion on Eating

Mastication is the first step in the digestive process of food. It is a mechanical function of breaking down the food into smaller particles by the teeth (English *et al.*, 2002). Poor masticatory ability may lead to limitation in types of foods that can be masticated and may produce changes in food selection (Wayler and Chauncey, 1983). Consequently, this might produce a health risk due to dietary restriction (Sheiham *et al.*, 1999) or over consumption of less healthy food – softer food higher in sugar and fat, although the evidence to support an impact on nutritional quality is lacking.

The relationship between malocclusion and eating problems is mostly related to masticatory ability and the occlusal relationship of the dentition in both arches to produce maximum contact and proper intercuspation. Good occlusion and intercuspation leads to better grinding of food and provides a larger surface area of food particles to be exposed to the enzymatic activity of saliva in

the mouth (Ngom *et al.*, 2007; Magalhaes *et al.*, 2010) and therefore, easier gastric emptying rate (Pera *et al.*, 2002). As such, correcting the malocclusion via orthodontic treatment which tries to optimise the occlusal contact by providing cusp-fossa interdigitation may accordingly improve the masticatory force (Magalhaes *et al.*, 2010).

Most of the studies that relate the masticatory performance to occlusal status rely on Angle's occlusal classification and some other studies used standard indices as a multiple trait combination (Khosravanifard *et al.*, 2012).

Age, body size, masticatory force and the number of posterior teeth have all been shown to affect chewing ability and biting force (Van der Bilt *et al.*, 1993; Julien *et al.*, 1996). Malocclusion and more specifically different types of malocclusion also play a role in the ability of mastication. Consequently, this may limit food intake and could in theory impact on nutritional status, as malocclusion may have a negative effect on the ability to breakdown food. A study which compared the relative masticatory abilities of different types of malocclusion (Class I, II, and III malocclusion) with normal occlusion, showed that subjects with normal occlusion had the best ability to break down food and those with Class I malocclusion had fewer difficulties followed by Class II and Class III malocclusion (English *et al.*, 2002). However, this study English *et al.* (2002) and some other similar studies (Shiere and Manly (1952); Owens *et al.* (2002)) have mostly focused on the incisor / molar relationship rather than the severity of the malocclusion. As a consequence, conflicting results emerged during the comparison between the malocclusion groups in relation to the masticatory performances (Toro *et al.*, 2006).

There are some other studies which described the masticatory efficacy and performance of orthognathic patients. Most of these studies indicated that there are differences between the orthognathic groups and the control group which is mostly class I skeletal and dental occlusion (Pancherz and Anehus, 1978; Ellis Iii *et al.*, 1996; Throckmorton *et al.*, 1996; van den Braber *et al.*, 2004; Abrahamsson *et al.*, 2015). Throckmorton *et al.* (1996) examined 117 patients (34 men, 83 women) undergoing different orthognathic procedures. The biting force of participants was examined before the surgery, then 6 months, 1 year, 2 years and 3 years post-surgery. They found that there is gradual improvement of biting force after surgery in comparison with pre-surgical records. However 6 months after the surgical procedure the biting force was lower than the pre-surgery. In contrast, a study on orthognathic patients with class II division I incisor relationship, reported no biting force change between before and after mandibular advancement surgery and one year after the orthognathic treatment, chewing performance was not improved. However, in comparison with the control group there was impairment of chewing performance, in agreement with other studies (van den Braber *et al.*, 2004).

The occlusal contact area can also affect the masticatory performance and ability. Yurkstas and Manly (1949) were one of the pioneer groups researching in this field who studied the relationship between occlusal contacts and masticatory performance. Having a larger occlusal contact area, especially on posterior teeth, is one of the main factors for having a good ability to break down the food if bite force and body size are excluded (Julien *et al.*, 1996). Therefore, individuals with normal occlusion who have a greater occlusal contact area show better masticatory performance and ability than those with class I, class II and class III malocclusions respectively (Owens *et al.*, 2002). In addition, individuals with a class III malocclusion tend to have less occlusal contacts which in turn reduces their ability to break down foods compared to those with other forms of malocclusion (Owens *et al.*, 2002).

2.3 Impact of Orthodontic Treatment on QoL

2.3.1 Introduction

Children's involvement in dental research is increasing (Marshman *et al.*, 2015). Most studies in the field of orthodontic treatment and QoL have focused on children due to the fact that they make up the majority of the patients who seek or are undergoing treatment (Zhou *et al.*, 2014). On the other hand, the number of adults seeking orthodontic treatment has increased dramatically. This is mostly because of the availability of such treatment and an increase in social awareness (Buttke and Proffit, 1999). In addition, general dentists have played an essential role in such remarkable increase by referring the susceptible patients to an orthodontist (Buttke and Proffit, 1999). Therefore, it is crucial for the general dental practitioners have enough information about the indications, contraindications and consequences of the treatment.

After orthodontic treatment has been completed, it is usual practice for a practitioner to assess the quality of care and whether or not pre-treatment aims have been achieved. In orthodontics the Peer Assessment Rating is generally used for this purpose. However, it is increasingly important to consider the opinions of patients in post-treatment assessments to assess their opinions on the quality of care and provision of the orthodontic therapy allowing them to express difficulties according to their experience. Patients may experience a variety of difficulties such as pain, functional and emotional difficulties and different kinds of discomforts which may vary with different types of appliances (Stewart *et al.*, 1997; Sergl *et al.*, 1998).

Aesthetic improvement is one of the main reasons for starting orthodontic treatment which generally results in a QoL improvement by enhancing the psychosocial well-being of the patients (Chen *et al.*, 2010). Patients who have acceptable dental aesthetics or those who have acquired favourable aesthetics via orthodontic therapy have reported the impact of their own preventive

behaviours by the attribution of their personal oral health. Furthermore, individuals with good dental aesthetics appeared to possess stronger perceptions about their oral health and better social interaction (Klages *et al.*, 2005).

The QoL of the patients is likely to be affected by orthodontic treatment. This effect will change according to the time of the treatment (Jones, 1984; Stewart *et al.*, 1997). Chen *et al.* (2010) studied the OHRQoL of patients at six different times before, during and after treatment. They concluded that OHRQoL during treatment was worse and the 1st week after insertion of the appliance showed the greatest OHRQoL deterioration. Subsequently, one month after appliance insertion the QoL gradually improved and reached the pre-treatment level, then after completion of the treatment the OHRQoL significantly improved.

Understanding the effect of orthodontics on QoL and assessment of OHRQoL is important because it enables:-

- Patients to understand the possible discomfort and consequences of the treatment as well as treatment needs.
- Understanding of patients expectations allows problems associated with non-compliance to be overcome more easily, resulting in better quality of care during treatment.
- An understanding of the benefits and effectiveness of orthodontic treatment and how to cope with treatment sequelae (Zhang *et al.*, 2008; Chen *et al.*, 2010).

A comprehensive systematic review of orthodontic treatment and QoL Zhou *et al.* (2014) reported that overall OHRQoL would be compromised for the first few months after insertion. During the first week after insertion, the level of physical pain, psychological discomfort, and physical disability reached the highest level. Therefore, the orthodontist and even general dentists should pay more attention to orthodontic patients and deliver good instruction regarding the possible ways to reduce the discomfort and deterioration in QoL. Although routine dietary instruction is generally delivered when an appliance is inserted, it should be delivered in a manner that both ensures the patient has enough food and to minimise the amount of discomfort that might occur during eating.

2.3.2 Orthodontic Treatment and QoL

The concept of QoL was broadened by the WHO in 1946 to include physical, mental and social well-being. Moreover, in England the Department of Health clarified this concept in relation to the oral health and stated “the standard of oral and related tissue health that enables individuals to eat, speak, and socialize without active disease, discomfort, or embarrassment, and that contributes to general wellbeing” (Department of Health, 1994). Therefore to evaluate an individual’s perspective, it is important that the subjective health measures be supplemented with the biological

measure of the diseases because quality of life and well-being have to be improved by any intervention (Berzon, 1998). OHRQoL was constructed according to the according to the Locker (1988) conceptual model. This model illustrated the consequence of oral diseases in which lead to psychological and social impairment. Moreover oral health can be regarded as an integral part of the general body health and any impairment in the oral health produce its impact on the general health (Gift and Atchison, 1995).

Assessment of the quality of orthodontic treatment can be improved by informative OHRQoL studies that help orthodontists and public health policy makers to pay more attention to the perceptions and feelings of the patient (Liu *et al.*, 2009). This can be approached by evaluating the treatment outcome measure according to both patients and clinical practitioners through evidence based health care (Hujoel, 2004). Therefore, QoL measure can act as a source of knowledge about the possible effect of orthodontic treatment on QoL. This may lead to a better understanding of the consequences of the treatment and its discomfort, as well as potentially improving compliance during treatment through the provision of better patient information (Sergl *et al.*, 1998; Zhou *et al.*, 2014).

The measured effect of orthodontic treatment on QoL may depend on the nature of the study for example cross-sectional or longitudinal studies. A systematic review on the relationship between malocclusion and orthodontic treatment with OHRQoL established that most previous studies are cross-sectional in design (Liu *et al.*, 2009). The reason behind this study design is an obsessive concern about the relationship of malocclusion with QoL rather than the outcome of the treatment (Liu *et al.*, 2009) which obviously needs to be evaluated after the orthodontic treatment has finished. On the other hand, according to Zhou *et al.* (2014) the number of longitudinal studies has increased which may be due to the different research questions and methodology of the search criteria. In cross-sectional studies the QoL is generally affected due to the time effect of the treatment which are mostly conducted during the start of the treatment. Whereas in the longitudinal studies the QoL score tended to increase which is indicate improvement in the QoL of the patients because of reducing complications during ongoing treatment (Zhou *et al.*, 2014). Additionally, most studies were conducted on children and adolescents aged between 11-16 years old rather than adults, because they are the majority of the patients who are seeking orthodontic treatment (Zhou *et al.*, 2014). Whereas the number of adult orthodontic patients is increasing (Buttke and Proffit, 1999), relatively little research has been undertaken assessing adult QoL, particularly in assessing psychological well-being (Klages *et al.*, 2006; Johal *et al.*, 2015).

2.3.3 Instruments used for exploring OHRQoL in Orthodontic Patients

It is clear that during orthodontic treatment, the situation of the patient will change with time. Sensitivity to change is an important determinant in any HRQoL measure to identify variation due to natural changes or clinical intervention (Ware Jr *et al.*, 1998). Therefore the instrument of choice should have a theoretical foundation with QoL and HRQoL to show changes between control and patient groups or between one group at two different times.

Most of the OHRQoL measures used for the orthodontic patient have been derived from other OHRQoL instruments. The best examples of these measures are Oral Impacts of Daily Performance (Adulyanon and Sheiham, 1997) and Oral Health Impact Profile (Slade, 1997). These instruments were initially developed for adults rather than for children. For example OHIP uses the word “denture” in almost all the questions which is not relevant to children. It also does not include any other questions which are important for children. Therefore, such measures are irrelevant to children with orthodontic appliances which excludes the majority of orthodontic patients.

Other tools exist which have been developed particularly for patients with a malocclusion and for both orthodontic and surgical orthodontic patients, for example the Psychosocial Impact of Dental Aesthetics Questionnaire developed by Klages *et al.* (2006) and the Orthognathic Quality of Life Questionnaire by Cunningham *et al.* (2000). Whilst these are generally more specific questionnaires for orthodontic patients, most have been developed for adults and adolescents aged 18 and above. On the other hand, a recently introduced Malocclusion Impact Questionnaire (MIQ) has been used by Patel *et al.* (2016) and Benson *et al.* (2016) for orthodontic patients aged 10-16 years old. In these two studies a patient based measure was used to extract the items of the questionnaire and children who were seeking orthodontic treatment participated in the validation of the questionnaire.

To overcome these problems attempts have been made to develop an instrument which is suitable for child orthodontic patients. Whilst several OHRQoL instruments have been developed for children, few of them are conjugated frequently with orthodontic studies in children:

- Child Perceptions Questionnaire (CPQ11-14) (Jokovic *et al.*, 2002)
- Child-Oral Impacts of Daily Performance (Child-OIDP) (Gherunpong *et al.*, 2004a)
- Child Oral Health Impact Profile (COHIP Child’s version) (Broder and Wilson-Genderson, 2007)
- Oral Aesthetic Subjective Impact Scale (OASIS) (Mandall *et al.*, 2000)

- World Health Organization Quality-of-Life Scale-Short Version, Medical Outcomes Study 36-Item Short Form (WHOQOL-BREF and MOS SF-36) (Ware Jr and Sherbourne, 1992; WHOQOL Group, 1998).

One of the commonly used OHRQoL instruments in orthodontic studies in children is the Child Perceptions Questionnaire (CPQ11-14) (Jokovic *et al.*, 2002). This is an outcome measure instrument developed to determine the changes at a group level during clinical trial studies rather than being unique to the individual which is regarded as the main challenge in QoL measurement (Locker and Allen, 2007). This instrument has been used and validated in different locations in the world such as Canada (Jokovic *et al.*, 2002; Jokovic *et al.*, 2005; Agou *et al.*, 2008b) New Zealand (Locker *et al.*, 2007), the United Kingdom (O'Brien *et al.*, 2006; Marshman *et al.*, 2010) and Australia (Do and Spencer, 2008). All of those studies were performed in a cross-sectional fashion, except the study by Agou *et al.* (2008b), which was a longitudinal study at two year intervals to assess the evaluative nature of (CPQ11-14). Although the sample size in this study was only 45 orthodontic patients, it was able to demonstrate that the instrument is sensitive to detecting change over longer intervals. In the UK this measure has also been applied to patients with malocclusion to find out the impact of malocclusion on the OHRQoL. Johal *et al.* (2007) reported the validity of the measure and its ability to be sensitive in contrasting the differences between patients with a malocclusion and a control group with no malocclusion.

CPQ11-14 consists of 4 domains which are oral symptoms (6 questions), functional limitation (9 questions), emotional well-being (9 questions) and social well-being (13 questions). The maximum score in CPQ11-14 is 85 and the minimum is zero, with higher scores indicating a reduced OHRQoL (Jokovic *et al.*, 2002). CPQ11-14 was used by Zhang *et al.* (2008) to detect the OHRQoL change during the first 6 months of fixed orthodontic appliances. The children completed CPQ11-14 5 different times, namely, before the treatment, after the 1st week, after 1st, 2nd and 3rd month successively. They found the most OHRQoL deterioration during the first months and the total score of CPQ11-14 increased in comparison with the pre-treatment records. The CPQ11-14 instrument is more generic and children should assess a wide varieties of oral and facial conditions. Therefore the instrument may not be sensitive enough to determine the impact of malocclusion on OHQoL and unconfirmed conclusion may be obtained if used on the solely orthodontic patients.

Eating related questions do exist in these instruments, but generally they are superficial questions. In CPQ11-14 three questions deal with eating problems enquiring about the stickiness of food to the dentition and soft tissues and about the duration of eating. The third question asks about the ability to drink or eat hot and cold foods. In comparison, the Child-OIDP consists of 8 questions

about daily performances in which the first one asks about how eating related issues impact on OHRQoL. The Child-OIDP is the next most commonly used OHRQoL instrument with orthodontic child patients. This is extracted from the original OIDP (Adulyanon and Sheiham, 1997) and face validity has been verified with child patients and content validity with pediatric dentists. This is to be sure about the words, language, sequence, response scale and the memory recall of the children. During validation, the memory recall was reduced from 6 months to 3 months and the 5-point Likert scale changed to a 3 point response format. The Child-OIDP is a direct application or modification of an adult measure in which the children are not involved in item generation and reduction and the items not obtained directly from children. This measure has been used on many occasions worldwide in cross-sectional studies. For example in Thailand (Gherunpong *et al.*, 2004a; Tsakos *et al.*, 2006), UK (Bernabe *et al.*, 2009), Peru (Bernabé *et al.*, 2007), and Brazil (Bernabé *et al.*, 2008a).

There are some differences between both CPQ11-14 and Child-OIDP in terms of age and the child's involvement in the process of item generation and reduction. The CPQ11-14 is directed at children aged 11-14 years old while the Child-OIDP was developed for 11-12 year old children. Moreover, Child-OIDP was derived from the adult version of the measure while the CPQ11-14 involved children in the process of the construction of the questions. However, both instruments ask children to recall the past 3 month's events (compared to 6 months often asked in adult questionnaires) and careful selection of words avoid negative word usage.

Bernabé *et al.* (2008a) used the Child-OIDP to determine the impact of wearing different types of orthodontic appliances on the prevalence and intensity of daily performances. The study was conducted on 357 Brazilian children aged 15 to 16 years. At least one daily living activity such as eating and speaking, was affected by the orthodontic treatment for nearly 90% of the participants. Fixed orthodontic appliances were claimed to produce more impact on daily performances rather than removable or combined appliances.

The OASIS deals with the concern of children about their teeth arrangement and assesses the impact of malocclusion on subjective QoL. A seven-point Likert scale is used as a scale of measurement for only 5 items about the appearance of the dentition. In this measure multidimensional aspects of OHQoL have not been emphasized and only 14-15 year old children were involved in testing procedure. Therefore wide range of QoL aspect and different children age who seek orthodontic treatment missed to be included in this measure (Mandall *et al.*, 2000).

Most of the earlier studies indicated negative changes and deterioration in OHRQOL due to the impact of orthodontic treatment. These studies also reported deterioration in issues related to eating

such as difficulties in chewing and biting due to the functional limitations. However, this matter has not been fully investigated and knowledge on ERQoL is still superficial and to discover these problems mainly relies on those OHRQoL measures which are not specific to exploring difficulties surrounding eating. Therefore, developing a new measure to assess ERQoL is warranted.

2.3.4 Orthodontics and Eating

Assessment of the success of orthodontic treatment beyond the professional description is essential to evaluate the pre-treatment goals. For that reason, a perception of the patient's experiences during the time of the orthodontic treatment is highly crucial as they may face discomfort, pain, and functional limitation (Sergl *et al.*, 1998).

The literature reveals that pain during orthodontic treatment is one of the obvious problems and some studies have linked pain with eating (Bergius *et al.*, 2002; Otasevic *et al.*, 2006). However, most of the orthodontic studies that used OHRQoL measures used generic instruments with limited questions about eating problems. Therefore, they cannot penetrate deeply and many eating-related issues are not explored, such as enjoyment of food, dietary habit change, and eating-related emotional feeling. The main difficulties that have been reported were functional, like biting and chewing problems as a result of pain in the dentition. In a cohort study by Otasevic *et al.* (2006) it was shown that the most common problem that faced adolescents during fixed orthodontic appliance treatment was eating difficulties (chewing and biting) and this was reported by the half of the participants.

Most of the patients who are receiving orthodontic treatment are children, particularly during the growth period. This period is regarded as a critical time for the growth of the human body and good nutritional supply plays a key role in this growth. Good oral health is one factor that may affect dietary intake and any oral health deterioration may produce its impact on dietary restriction (Acs *et al.*, 1992). Furthermore, the dental health condition can influence QoL (Sheiham *et al.*, 2001; Tsakos *et al.*, 2012). On the other hand, dietary intake also influences physiological and behavioural responses through its effect on the energy level of the body. If dietary intake is inadequate, a series of responses occur such as reducing the volume of fat and muscle and lowering body weight (Shetty, 1999).

2.3.5 Dietary Intake Studies in relation to Orthodontic Treatment

To date, there are few studies investigating dietary intake and its effect on orthodontic treatment. The earlier studies mostly focused on quantifiable data about dietary intake during orthodontic treatment. The relationship between dietary intake and orthodontic treatment has been investigated and briefly discussed in outdated and poorly designed studies (Cheraskin and Ringsdorf Jr, 1969a; Cheraskin and Ringsdorf Jr, 1969b). In the first study, 17% to 53% of 139 child orthodontic

patients demonstrated less than optimal levels of vitamin C when measured by plasma ascorbic acid. While in the second study, approximately 72% of the patients were verified with sub-optimal vitamin C level status when checked by the lingual vitamin C. However, for the retention of orthodontically moved teeth, vitamin C has a role and its deficiency may increase the risk of the relapse (McCanlies *et al.*, 1961). In another study, Riordan (1997) found only statistically significant differences between manganese and copper levels in diet in the three days after insertion of the orthodontic appliances. The sample of this study was small and they only investigated 10 patients aged 12 -16 years old. In addition, this study indicated that participants shift to fat-rich and low carbohydrate soft diet in comparison with their control diet at pre-treatment time. However, these changes did not reach statistical significance. This is may be due to the sample size which was only 10 participants and the duration of the intervention which was only 3 days for assessing the nutrient intake.

The next generation of studies investigated the relationship between orthodontic appliances and OHRQoL and some of these studies included elements relevant to eating. Mandall *et al.* (2006) studied the effect of fixed orthodontic appliances on daily life in 66 orthodontic patients at three successive visits after bonding the fixed appliance. In the OHRQoL questionnaire used, there was a sub-scale about the dietary impact of orthodontic appliances; however, it was not a condition-specific instrument as it contains other questions that are not relevant to eating and dietary problems. Therefore, it is difficult to measure the exact patients perceptions and experiences about eating related issues. Moreover, in another study de Oliveira and Sheiham (2004) used two QoL measures the OIDP and OHIP-14 and showed that nearly half of the patients, who reported oral health problems, linked dental pain during eating as the most frequent reason for deterioration of OHRQoL. Zhang *et al.* (2008) undertook a study on OHRQoL during orthodontic treatment. CPQ11-14 was used as an OHRQoL instrument on 217 patients at four different times during the first 6 months of treatment. There were only two questions about eating difficulties under the functional limitation and oral symptoms domains and one question about the problem with hot or cold drinks and foods. It is obvious that, a few broad questions cannot capture the wider implications of orthodontic appliances on eating. Therefore, there is a need for a study which explores the wider eating related issues during the course of the treatment incorporating the patient's experiences and perceptions.

Johal *et al.* (2013) conducted a study about the effect of fixed orthodontic treatment on the child's diet. In this study, dietary intake behaviour, body mass index (BMI) and bioelectrical impedance analysis were used to measure the change in fat percentage as an indicator for dietary deterioration. The sample was divided into control and test groups. The total sample size was 124 and the

participants were aged 11-14 years old. For dietary intake behaviour, a Food Frequency Questionnaire and Socioeconomic Status questionnaire were applied, pain intensity, patients' height and weight, body weight and fat percentage were also measured in both groups. At baseline, after 4-6 weeks and 3 months these measures were repeated in both groups. Test group children were also asked to complete the pain experience and dietary change questionnaires that were developed by Abed Al Jawad *et al.* (2012). Patients BMI index in the test group was decreased and in the control group increased. It is difficult to relate this change to the orthodontic treatment alone because there will be normal physiological changes during this period of a child's growth. Although the above study covered some of the important topics about eating and dietary change that are associated with patients during the course of treatment, it can be criticised for its sampling technique in which patients from multiple ethnicities were recruited, whilst accepting that this may increase the generalisability of the results. In addition to that, measuring orthodontic-related physiological changes of the body may be difficult to measure, particularly during the period of growth of children and finally, the dietary questionnaire captured only pain experiences and physical issues for the dietary changes. Other aspects of QoL measures were not measured such as psychological, social, and emotional characteristics.

Orthodontists impose some recommendations on patients at the start of the treatment and sometimes these recommendations continue until the end or even after the treatment. In general, most of these recommendations are delivered in the form of verbal and written instructions. The two important topics which it is common to see in such recommendations are oral hygiene and dietary instructions. Dietary instructions tend to focus on the soft diet and avoiding hard and chewy foods so as not to harm the appliance and to minimise the anticipated discomfort and pain. Furthermore, orthodontists may apply very strict preventive measures and oral hygiene strategies after eating to prevent periodontal and dental disease at the time of the treatment. These measures may affect the dietary intake, quality and quantity of the consumed foods and drinks and it is essential to confirm these changes in the orthodontic patients own words.

2.3.6 Summary

In the last few decades an extensive body of literature has appeared focusing on the patient-centeredness notion in both medical and dental healthcare settings, emphasizing patients perceptions rather than the traditional biomedical model (Mead and Bower, 2000). This notion takes into account the patient's perception of their conditions or diseases in association with their physical and psycho-social experiences. Therefore patients are central in determining the health need and the success of an

intervention or treatment and overall HrQoL (McGrath and Bedi, 1999; Locker, 2004; Newsome and McGrath, 2006).

Orthodontic intervention has a history of more than 100 years and has proved to be an effective and successful treatment method. However it is important to know how the orthodontic patient accepts the treatment and how they deal with the possible side effects of the treatment. The most common side-effect of the treatment is pain in their dentition due to the applied pressure on the teeth which is mostly perceived at the start of treatment (Sergl *et al.*, 1998; Bartlett *et al.*, 2005; Polat, 2007; Bergius *et al.*, 2008; Rakhshan and Rakhshan, 2015). In addition to that oral ulceration, functional limitation, difficulty in swallowing and impairment of daily activities alongside negative OHRQoL are other possible setbacks during orthodontic treatment (Doll *et al.*, 2000; Sergl *et al.*, 2000; Mandall *et al.*, 2006; Zhang *et al.*, 2007; Chen *et al.*, 2010). Therefore it is a research priority to investigate the consequences of these side effects on patients QoL to provide evidence for improving the quality of care during orthodontic treatment. Adherence to particular treatment can be increased by understanding the experience of the patient which will also improve the patient's attitude and adaptation to the treatment (Robinson *et al.*, 2008).

Children are the majority of the patients who are receiving orthodontic treatment, particularly during the growth period. This period is regarded as a critical time for the growth of the human body and a good nutritional supply plays a key role in this growth. Good oral health is one factor that may affect dietary intake and any oral health deterioration may produce its impact on dietary restriction (Acs *et al.*, 1992). Few OHRQoL measures have been developed to indicate the QoL of children during the course of orthodontic treatment. CPQ is one of the most commonly used instruments for children (Jokovic *et al.*, 2002) and has been validated in different geographical locations (Jokovic *et al.*, 2005; O'Brien *et al.*, 2006; Locker *et al.*, 2007; Agou *et al.*, 2008b; Do and Spencer, 2008; Marshman *et al.*, 2010).

At the present, the literature suggests OHRQoL deterioration occurs during the course of orthodontic treatment and pain is the most common complaint patients raise particularly during eating. However, this issue is still unclear and further investigation is necessary to broaden our understanding of patient's experiences of eating related difficulties during orthodontic treatment through qualitative research and development of an instrument to measure the impact of the treatment on ERQoL during the period of fixed orthodontic treatment.

3 Chapter Three: Research Questions, Aim, Objectives and Research Plan

3.1 Research Questions

How can orthodontic appliances affect ERQoL of patients undergoing orthodontic treatment?

How can these impacts be measured efficiently in a shorter period of time and on a larger sample?

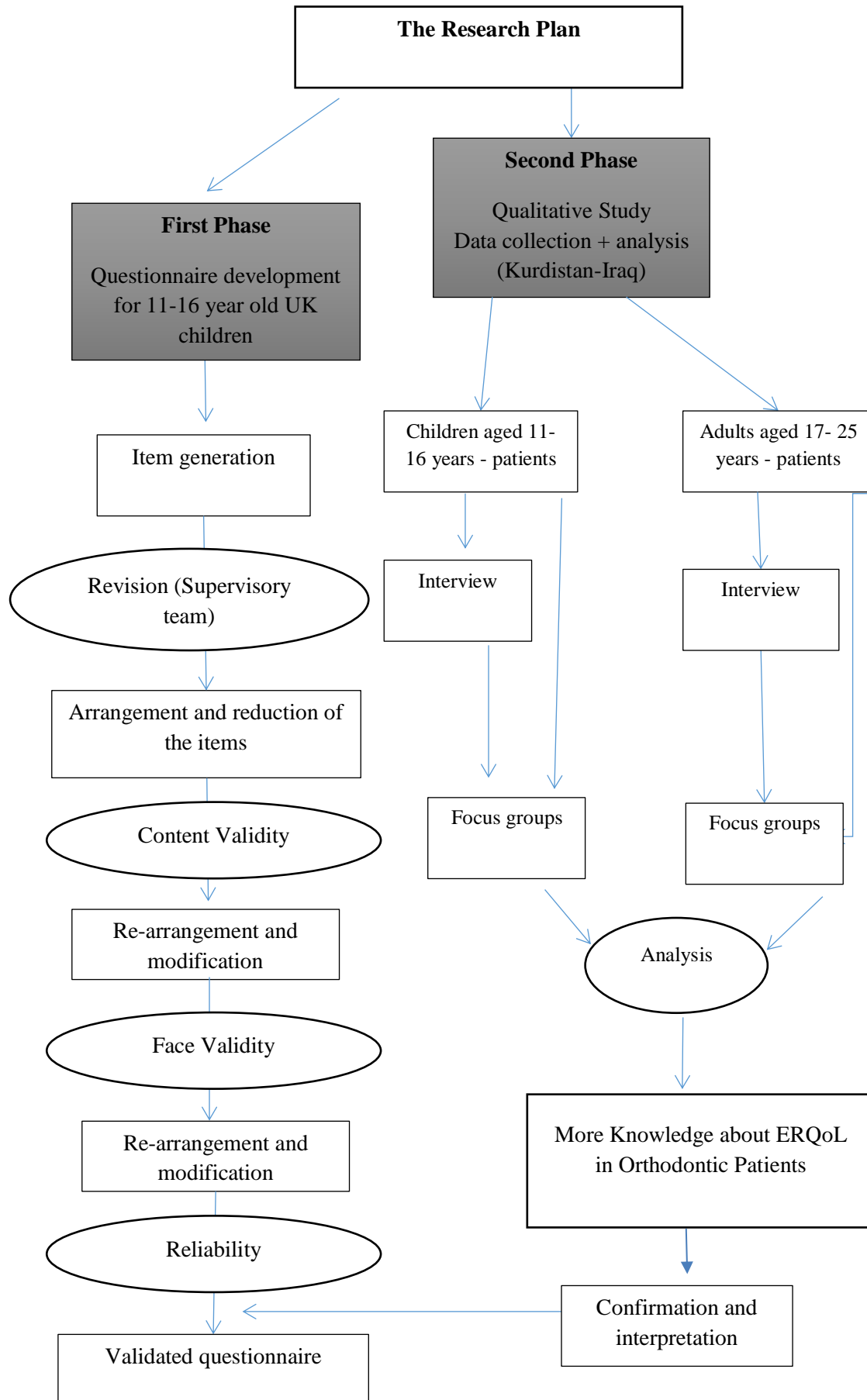
3.2 Aim

To explore ERQoL of patients undergoing orthodontic treatment by conducting a new qualitative study in Kurdistan-Iraq and developing a new outcome measure in the UK.

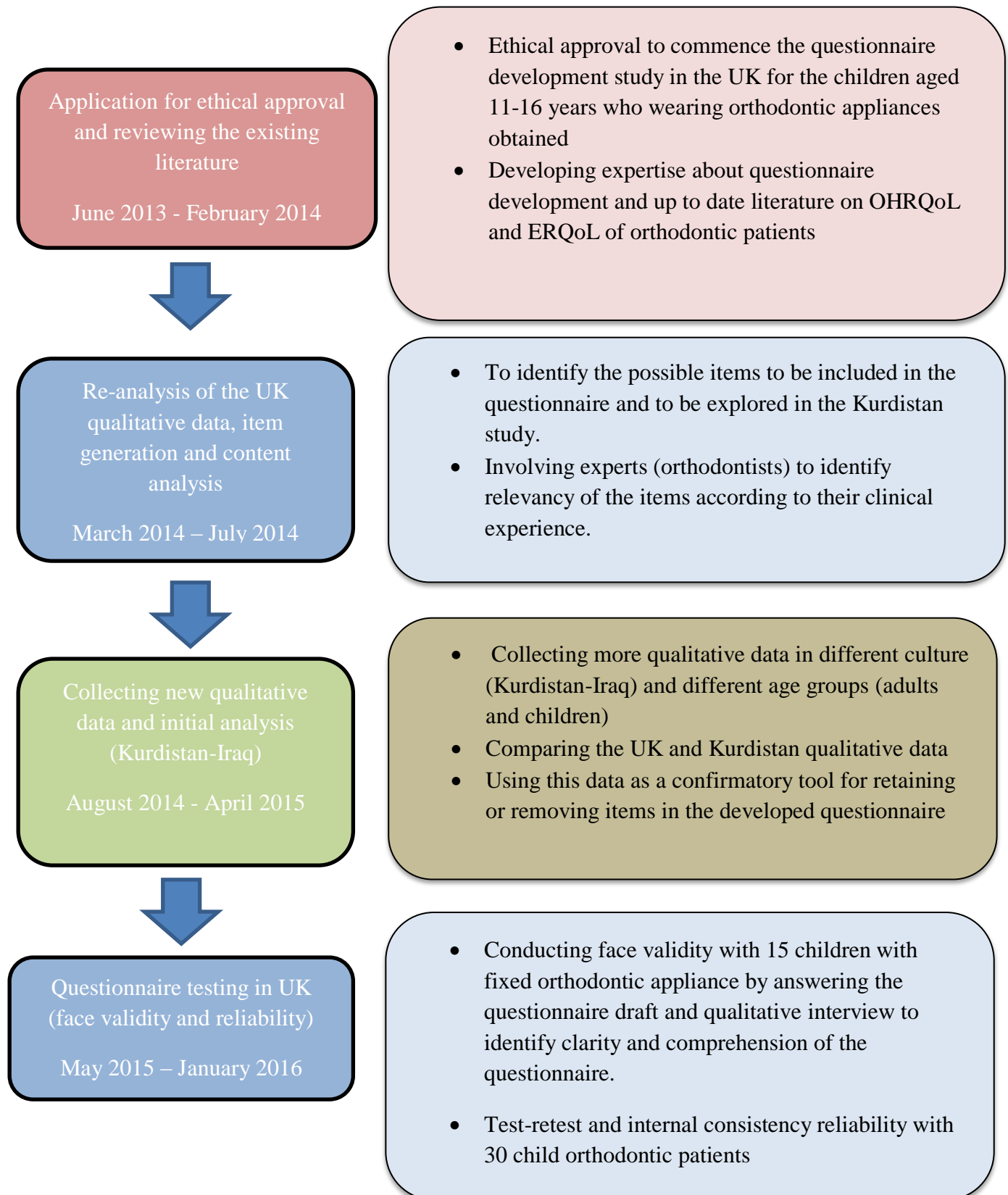
3.3 Objectives

- To use existing qualitative data to develop and validate a questionnaire to measure ERQoL in UK children.
- To use semi-structured interviews and focus groups to obtain new qualitative data on the impact of orthodontic treatment on ERQoL in Kurdish adult and child populations. This study will be used to identify possible new themes and confirmation of items that should be included in the newly developed measure for UK children.
- To compare existing qualitative data in a UK population with data collected from a Kurdish population to determine common culture and age specific themes.
- Based on the findings, provide an example for appropriate dietary instructions.

3.4 The Research Plan



3.5 Time line of the PhD study



4 Chapter Four: Development of a Questionnaire to Assess ERQOL in a Population of English Orthodontic Patients

4.1 Introduction

The questionnaire construction process is a multistep process and should involve several steps to complete a scientific based instrument to measure the patient's outcome. It is important to ensure that the questionnaire can be easily understood by the study target age group (11-16 year olds). Children in this age group are relatively homogenous in terms of roles and cognitive abilities, allowing the production of a single questionnaire to capture the experiences of a large range of orthodontic patients. Guyatt *et al.* (1986) provided an approach for developing a patient based specific questionnaire for measuring the QoL of the patients. Guyatt *et al.* (1986) made some suggestions about the construction of specific outcome measures and broadly stated "Items on the questionnaire must reflect areas that are important to patients suffering from the disease and therefore should be derived from what patients say about how the illness affects their lives". The general principles of this approach have been used on different occasions with relatively different approaches (Baker *et al.*, 1993; Cunningham *et al.*, 2000; Kelly *et al.*, 2012; Shelton *et al.*, 2015).

The development of the questionnaire in the current study was underpinned by data from a previous qualitative study conducted by the supervisory team (Carter *et al.*, 2015). The study was performed at the Newcastle Centre for Oral Health Research (COHR). Focus groups and semi-structured interviews were employed with 11-14 year old patients with orthodontic appliances. The sample was 19 patients with removable, functional and fixed appliances. Three focus groups and 13 interviews were conducted. The mean time for the interviews was 11 minutes and for the focus group was about half an hour. The aim was to obtain in-depth qualitative data regarding the impact of orthodontic treatment on ERQoL. The patients were asked open questions about the eating difficulties they had experienced with orthodontic appliances and about the functional, psychological and emotional impacts of these difficulties.

4.2 The Aim and Objectives of this Study

The aim of the current study was to develop a patient based measure for exploring the ERQoL of the child orthodontic patients aged 11-16 years old with different types of appliances.

The objectives of this study were to conduct the following phases:

- Content validity
- Face validity
- Reliability by a) test re-tests to indicate the stability and reproducibility of the questionnaire and b) alpha correlation to determine internal consistency of the questionnaire

4.3 Subjects and Methods

In order to develop the questionnaire several steps were followed in an iterative process of questionnaire development and questionnaire testing. The process included different qualitative and quantitative approaches involving patients and experts in the field of the study. The steps were as follows

- Item generation and selection
- Item reduction
- Questionnaire format
- Pretesting

4.3.1 Item Generation and Selection

Existing qualitative data on the impact of orthodontic appliances on ERQoL was used to generate the items (Carter *et al.*, 2015). In order to be more confident about the relevance of the analysis of the previous qualitative study, the audio files and transcriptions were examined and compared with analysis of the qualitative data. A qualitative framework analysis was performed to determine the analytical themes and to develop an index for extracting the questions. The analytical index was used as a framework for the initial questions (the detail of framework analysis will be discussed in the subsequent chapter).

At the start of the question or item generation several kinds of response scale were considered. Intended measurement scale consisted of two nominal scales, two ordinal scales and one qualitative answer option. The nominal scales were Yes/No and Multiple Choice Questions (MCQ) which needs simple check or selection of the provided answer. The ordinal scales were VAS and Likert scale. The last response option was purely qualitative and requested detailed free text answers from the participants.

Combining different kinds of scales in a questionnaire could introduce difficulties for the respondent to indicate their answers and may make analysis of the answer harder for the researcher. McDowell (2006) indicated that when any measurement contains several types of scale the interpretation of the result score will not be clear. Therefore during the next stage the items were reduced and the most appropriate response scale for the questionnaire was selected.

4.3.2 Item Reduction, Selection and Modification

The aim of this phase was to reduce the items so as to include only relevant and comprehensible items. The first line in the item reduction was conducted by the researcher and supervisory team. The first draft of the questionnaire was prepared by the researcher according to the framework

developed from the analysis of the UK qualitative data. The first draft of the questionnaire was passed to the supervisory team for revision and comments and possible amendment.

At this stage, some of the questions were rephrased in order to be more simple and understandable by children and exclude any language barrier that may have occurred with the principal researcher during construction of the questions. Two sets of questionnaires were constructed with the same items, but with different measurement scales, one with VAS and the other with 5-point balanced Likert scale. One of the scales was to be selected according to the decision of the experts during the content validity and according to the opinion of the child orthodontic patients during the face validity stage.

4.3.3 Content Validity

For content validity stage, 12 orthodontic consultants and trainees participated. The questionnaire drafts were sent to them one week before a meeting in which the researcher presented the aims of the study and the questionnaire items one by one in the form of a seminar. The researcher asked them to comment and rate the relevancy and comprehension of the items according to their experience of orthodontic treatment. Furthermore, they were asked to give their opinion about the most appropriate rating scale for the final version of the questionnaire and if possible give the reason for the selection. One of the points that should be taken into consideration is that content validity should be directed towards the selected population because it may be different from other populations. The measure that is more representative of a selected sample creates a more accurate inference (Messick, 1990). If the content validity of an instrument is high, it has a wide range of inferences for the sample or group of samples in different conditions and situations (Streiner *et al.*, 2015).

In the Content Validity Index (Wynd *et al.*, 2003) a four point Likert scale (*not relevant, somewhat relevant, quite relevant, and very relevant*) was used to assess the content validity. The same idea was also implemented for the clarity of the items by having *not clear, somewhat clear, quite clear, and very clear* options. Taking a closer look at these four categories, it can be seen that the first two options are representing a *No* answer while the last two options are representing *Yes* response (Waltz *et al.*, 2010). This is because the responses *somewhat clear* or *somewhat relevant* still give a negative view toward the items therefore, it would be questionable whether such items should be included as they may affect the validity of the process and vice versa for the *quite relevant, or quite clear* answers. As such the options *not relevant, relevant and not clear, clear* were used during the rating and for the retention of the items any item rated for relevancy and clarity by more than 80% of the participants was retained from the questionnaire. This is nearly a similar procedure to that performed by Blackwood and Wilson-Barnett (2007) and Kelly *et al.* (2012).

The best way to start a test on the questionnaire content, is seeking the opinions of experts in that field of study (Streiner *et al.*, 2015). Messick (1990) mentioned that “content validity is based on expert judgments about the relevance of the test content to the content of a particular behavioural domain of interest and about the representativeness with which item or task content covers that domain”. This concept is also in agreement with other authors who preferred judgment by experts in the field during content validity testing, whilst not including them in the face validity stage (Nevo, 1985).

The content of the questionnaire was checked qualitatively by asking the orthodontic consultants and trainees to comment about the items, especially those items which they considered to be not clear or irrelevant. As well as giving comments verbally during the presentation some of the experts offered their comments on the hard copy of the questionnaire which had been sent to them one week earlier. All the comments were used to revise the questions, the format of the questions and measurement scale, the layout of the questionnaire and for adding new questions.

4.3.4 Questionnaire Format

a. Instruction Page

In order to guide the participants to answer the questions in the right way, a simple and short instruction page was provided for the children. There were some instructions about how to answer the questions, how to indicate the answer on the response scale and how to add more explanation about the answer in the free text areas.

b. Response Scale

Likert scale and Visual Analogue Scales (VAS) were considered most appropriate for use in this research. In addition to that, a free text option was also selected to be included with the selected quantitative scale to give a more qualitative explanation for the given answers (Figure 4.1).

In order to make the VAS more comprehensible for the children, visual aids in the form of cartoon faces were added to the end of the line under the extreme labels. These visual aids are regarded as a quick glance aid for to help respondents to understand the idea of the extreme labels quickly and attract their attention to the answers (Dillman, 2007).

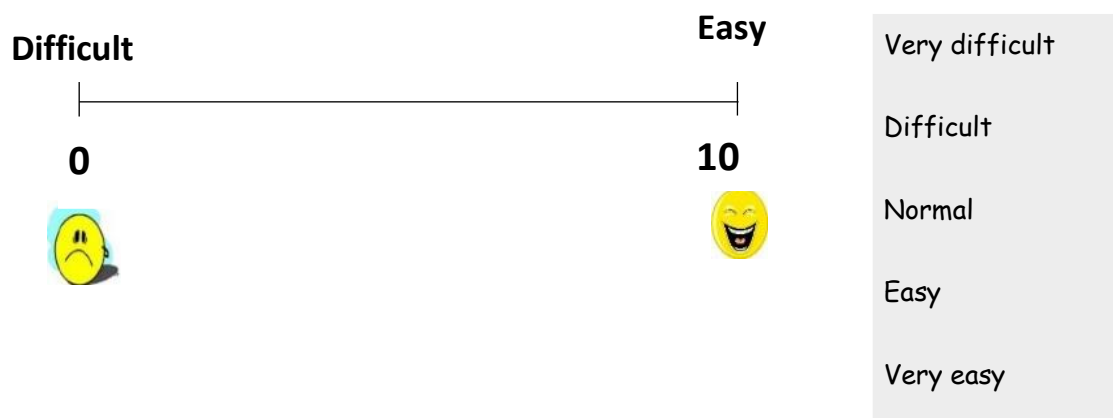


Figure 4.1 An example of the VAS and Likert scale used in this study

For the selection of the response scale two different procedures were performed. Firstly the orthodontic consultants and trainees were asked to choose one of the two given scales for the questionnaire and give the reason for their choice during the content analysis stage. Secondly, a short-informal interview was held with 5 child orthodontic patients at the Newcastle Dental Hospital/Orthodontic Department. They were shown a sample of selected questions with both scales and asked to give an indication of the scale which they think would be easiest for them to understand or to answer. The most appropriate scale for this age group was then used for the questionnaire.

In addition to the response scale, free text options were also provided for each question. This is an optional choice and it was provided to enable respondents to give more explanation about their given answer. It gives the researcher a more qualitative response and greater explanation of the quantitative answers.

c. Items Format

Children aged 11-16 were recruited and 10 years old was aimed reading age to accommodate lower ability readers within that age group. The sequence and the order of the questionnaire was organised in a way that the participant can easily follow it. Questions that were easier to answer were placed first and then the more specific questions were listed at the end of the questionnaire according to the format indicated by Bowling (2009). The functional questions which ask about physical difficulties during eating appeared in the first pages of the questionnaire and the last pages contained questions about the enjoyment and psycho-emotional feeling of eating during the course of orthodontic treatment. In order to enhance the response rate and increase the comprehension of the questions by the respondents the question language aimed to be simple, without medical terms and jargon, using as short sentences as possible (Oppenheim, 1992; McColl *et al.*, 2001).

A Flesch reading score Flesch-Kincaid Grade Level was used to determine the reading acceptability for the selected children's groups aged 11-16 years old. This test depends on the average length of a sentence according to the word numbers and the word average length according to the syllable numbers (Friedman and Hoffman-Goetz, 2006). Both of the tests were calculated using a function which is present in Microsoft word. The formula of both of the tests is as follows:

$$\text{Flesch Reading Ease score} = 206.835 - 0.846 \text{ tw/ts} - 1.015 \text{ tsl/tw}$$

$$\text{Flesch-Kincaid Grade Level} = 0.39 \text{ tw/ts} + 11.8 \text{ tsl/tw} - 15.59$$

tw= total words

ts= total sentences

tsl = total syllables (Flesch, 1948)

d. Questionnaire Layout

To attract the participant's attention to the questionnaire and enhance the response rate a light green coloured paper was selected for the questionnaire with the questions printed in black. The visual aids in the VAS were also printed in colour to enhance attractiveness and the questionnaire was printed in a booklet format rather than a handout style.

4.3.5 Ethical Consideration

Ethical approval for the questionnaire development study was obtained from the NRES Committee North West - Liverpool Central (14/NW/0315) (appendix B1) and Directorate of Research and Development at Newcastle Upon Tyne Hospital NHS Foundation Trust (7007) (appendix B1).

4.3.6 Consent procedure

The consent form and assent form (appendix C1) were developed by the researcher for completion by both parent/caregiver and the children, using a template based upon the guidelines of R&D at Newcastle Upon Tyne Hospital NHS Foundation Trust. The researcher also participated in a course held in the Dental School at Newcastle University about taking consent from the patient for research purposes. The signed consent and assent forms were returned back to the researcher by the interested participants after reading the provided information sheets. The child information sheet was constructed to be as simple as possible and three orthodontic patients of an appropriate age were invited to read and indicate their possible comments on the child information sheet. This procedure was conducted before starting to send or give the information sheets to the participants. A copy of the signed form and information sheets was preserved inside the patients' medical records.

4.3.7 Confidentiality

The issue of confidentiality was emphasised and a coding system was used to preserve the identity of the participants in both phases. An identification number was used for the questionnaires, return envelopes and audio recorded files rather than the informant's name. These numbers were linked to the respondent's name in a separate list that was stored in the research file in a secure place in the researcher's office. All participants and parents/guardians were informed about this subject verbally and this was detailed in the participant information sheet.

4.3.8 The recruitment process

After receiving all the necessary approvals, participant recruitment started. All participants were recruited from the orthodontic department at Newcastle Dental Hospital for both the face validity and reliability testing phases. The appropriate patients were identified from the clinical diaries of the clinicians in the hospital, according to the inclusion and exclusion criteria of the study (Table 4.1).

Orthodontic patients aged 11-16 years were selected to participate in this study, because they represent the majority of patients who receive NHS orthodontic treatment. During their routine clinical appointment the clinical care team introduced the study to the orthodontic patient and the parent/caregiver. The role of the clinical care team in recruiting patients to this study can be summarised in three points:

- Identifying the eligible patients from their clinical diaries.
- Introducing brief and quick information about the study to the parents/ caregivers and the patients.
- Finally introducing the patients and their parents/ caregivers to the researcher.

After the end of the clinical session the researcher introduced himself to both patients and parents/ caregivers and presented the aims and the background of the study. For those who were interested in the study an information sheet was given to both patients and parents/ caregivers. The information sheets provided detailed information about the study and the required actions by the participants (appendix D1). After reading the information leaflets and a short discussion with each other (patients and parent/guardians) the researcher invited them to ask any further questions, before asking for their final decision regarding willingness to participate (Figure 4.2.)

Table 4.1 Inclusion and exclusion criteria for the sample of the questionnaire development study

Inclusion criteria	Exclusion Criteria
Patients wearing orthodontic appliances.	Severely visually impaired or deaf to an extent that would make comprehension and completion of the questionnaire and the interview impossible.
Age 11-16 years.	Conditions that have impact upon dietary intake
Live in the UK	Unable to complete assent form
Able to speak, read and write in English without the use of an interpreter.	Parent unable to complete consent form

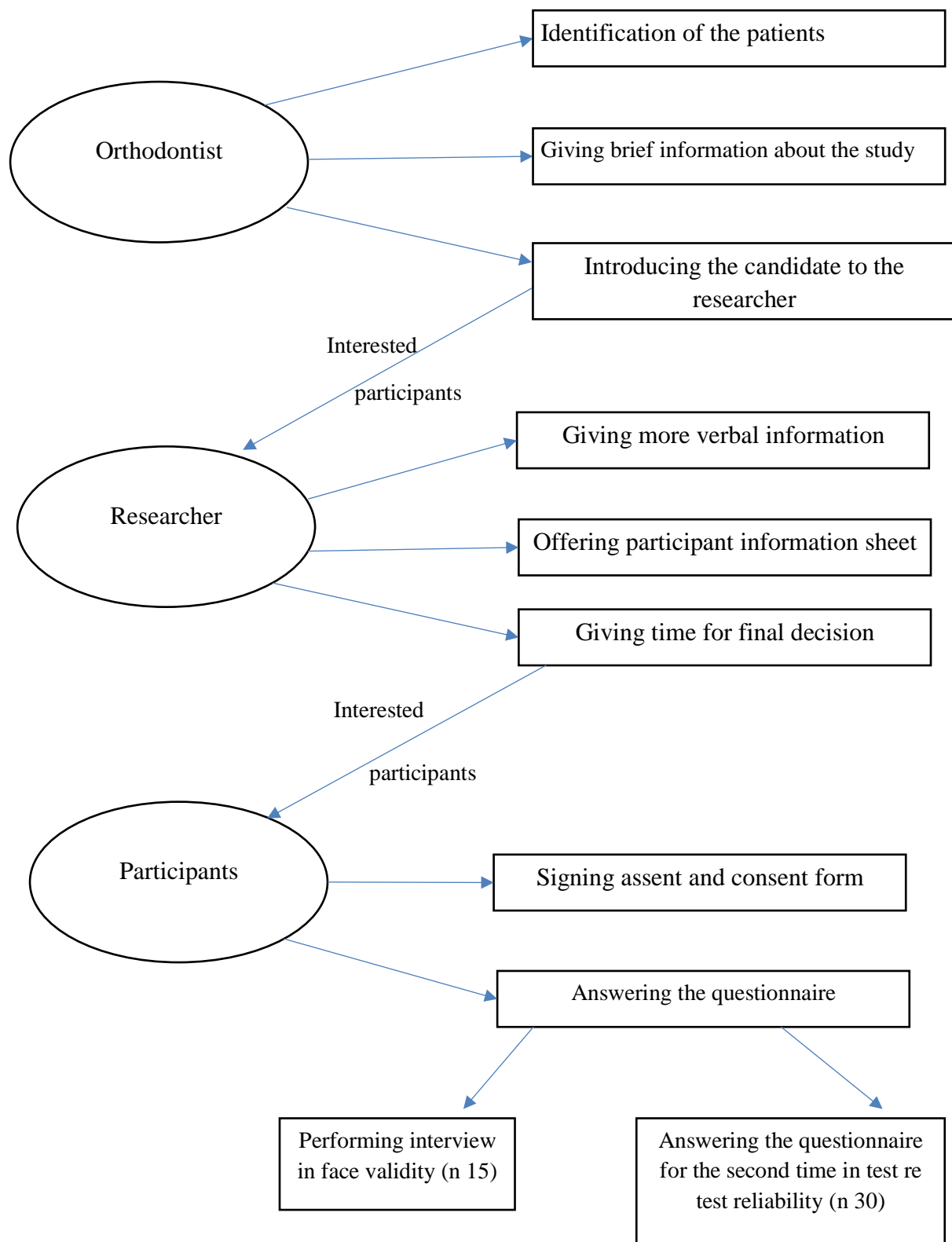


Figure 4.2 Recruitment and data collection process

4.3.9 Face Validity

Child orthodontic patients in this phase were asked to determine the complexity of the items and to clarify what type of information the questionnaire aims to receive from the respondents. This phase of the study aimed to recruit 15 patients aged 11-16 years old, including both boys and girls with orthodontic appliances in different stages.

According to Nevo (1985) face validity can be performed using two different methods, “absolute” and “relative”. In the absolute method which is mostly quantitative, the participant will be asked to rate the questions or items using a scale such as a 5 point scale. Whereas the relative method which is more qualitative, the raters judge and have the opportunity to express their opinions about the questions or items.

Before participants started answering the questionnaire the researcher assured them that there are no right or wrong answers and the aim of this process is to test the questionnaire not the patients. Additionally the researcher was present during the questionnaire completion and informed the participants that they are free to ask for clarification if they were struggling with understanding any of the questions or they can skip or mark those question(s) for discussion of problems during the interview if they found difficult to understand or they felt were not relevant to their experiences with their brace. When participants finished answering the questionnaire, the researcher asked the participant to indicate the clarity and relevancy of the questions using the same procedure described in (section 4.3).

The instrument can be validated qualitatively by taking the opinions of patients and avoid having only to rely on quantitative methods for determining validity (Mallinson, 2002). The face validity phase included a qualitative semi-structured interview with the same participants after they finished answering and rating the questionnaire. The interviews were mainly about the experience of the respondents during answering the questionnaire and assessing qualitatively any difficulties they found in understanding the meaning of the questions and its comprehension, clarity and relevance. Furthermore, the children were asked for their general opinions about the questions and if they had any further recommendations like adding new questions or rephrasing the current items, their opinion about the rating scale and the appearance of the questionnaire. These interviews were recorded, transcribed and analysed by the researcher and their recommendations and suggestions reported and implemented in the questionnaire.

Interviews and questionnaire answering for both phases was performed in a quiet corner of the orthodontic department at Newcastle Dental Hospital so as to record the interviews with minimum background noise. Each participant was informed of the rationale behind the audio recording before the interview commenced, and they were encouraged to explain the topic as much as they

could. All the participants were accompanied by their parent/guardians during the recording. Some parents/guardians expressed their comments, but these were not included in the analysis, because for this phase of the research it was the children's own perspectives that were important. Parental interruption was often used to probe the information from the patients perception during the time of the data collection. Although the presence of a close family member might influence participants' responses, it was felt to be more important that participants were as comfortable and confident as possible during the process. Therefore, all the participants were allowed to be accompanied by their parent/guardians during questionnaire completion.

A topic guide was prepared in advance and had been discussed with the research team. The topic guide was intended to encompass all areas that could be related to the questionnaire, clarity and comprehension (Appendix E3).

4.3.10 Reliability

Reliability is an important step in an instrument or questionnaire construction, and it deals with stability and consistency of the results. It can be defined as a “measurements of individuals on different occasions, or by different observers, or by similar or parallel tests, which produce the same or similar results” (Streiner *et al.*, 2015). Following statistical advice and based on similar studies which recruited 24 (Cunningham *et al.*, 2000) and 30 participants (Kelly *et al.*, 2012) for validity testing, this study aimed to recruit 30 participants to participate in the reliability testing phase.

There are different methods for testing the reliability of a questionnaire. According to Jacoby and Matell (1971) providing a meaningful and complete response from the respondents needs an assessment of internal consistency (reliability coefficient) and test-retest reliability (stability). Reliability deals with the questionnaires repeatability, stability or its internal consistency. It depends on the type of the test and the sample that is going to be tested. It is the researcher's responsibility to provide an instrument with minimal chance of error and maximum likelihood of obtaining reliable data (Colton and Covert, 2007) and consequently, a rigorous result may be achieved (Langdridge, 2004).

a. Test-retest Reliability

In this test 30 participants who were currently undergoing orthodontic appliance treatment answered the questionnaire on two different occasions. The first time was during their routine visit to the orthodontist. A two week interval was selected to send the questionnaire back to the participant to obtain their second response. The time span between two data collection periods in test-retest reliability depends on the type and the nature of the study and it varies between 2-14 days (Streiner *et al.*, 2015). Generally the time span should not be too long as the response of the participants may

change over a long period of time, and this in turn will impose its effect on the repeatability of the questionnaire. In contrast, the time span also should not be too short because the respondents may memorise their previous answer and this could interfere with their second answer (Nunnally and Bernstein, 1991; Brace, 2008). Memorising the previous answer by the respondents is one of the shortcomings of this test and “practice effect” may impose its influence on the participant’s answer, because they have learned how to practice or respond to the questions (Langdridge, 2004; Lemay *et al.*, 2004). Therefore, it is essential also to perform another test of reliability which is not dependant on the time to compliment the test retest reliability (Hendrickson *et al.*, 1993).

Test-retest reliability can be measured by either Intra class correlation coefficient (ICC), paired t-test or Pearson correlation. ICC was used to determine the correlation between the two occasions at domain level and both paired t-test and Wilcoxon signed ranks test at question level to calculate any difference between the questions mean for each participant between occasions, according to the normality of the data distribution Streiner *et al.* (2015) indicated that ICC may be a better choice rather than the Pearson correlation due to the fact that the Pearson correlation always gives a higher measure than the true reliability. In test-retest reliability, the same respondents answer the questions on different occasions, so they are dependent. Paired t-test will also deal with dependant variables when the occasions are in pairs such pre and post intervention results (Hsu and Lachenbruch, 2007). If the data are not normally distributed Wilcoxon Signed Ranks test is the method of choice as an alternative to paired t-test as a non-parametric test (Handforth *et al.*, 1998).

b. Internal Consistency Reliability

Cronbach’s alpha was used to determine the internal consistency reliability of the instrument. This test is probably the most popular measure to determine the reliability of an instrument. This is mainly due to the nature of this test which does not need two or more raters or more than one time administration of the scale, in contrast to test- re test reliability, which needs two different time applications of the instrument to the same informants or different informants in inter-rater reliability test (Streiner, 2003). Alpha correlation will be affected by other factors such heterogeneity of the sample, which decreases the value of the correlation and the item numbers which mislead the value and may give a satisfactory impression of internal consistency. Lastly, a very high value of such as 0.90 may indicate unnecessary redundancy of the items which likely needs shortening to produce a reasonable length questionnaire.

Generally, if the score is greater than 7 (>0.7) it means that the measurement of the scale items has a good relation with related construct. Malhotra & Birks (2007) indicated that if the value of Cronbach’s alpha (α) < 0.6 it means that internal consistency reliability is unsatisfactory. Whereas Nunnally and Bernstein (1991) indicated that 0.5-0.6 are acceptable correlations, particularly at

the early stage of the research. As such, over emphasizing the importance of internal consistency may lead to removing items which could be crucial for the questionnaire (Fitzpatrick *et al.*, 1998).

4.3.11 Reliability Sample and Design

For the reliability testing, a new sample of patients (not those approached for the face validity phase) was recruited and 30 patients showed their willingness to participate in the study. At the time of recruitment, participants were made aware that the estimated time to complete the questionnaire was 15 minutes and that they would be offered £25 for completing the study.

Participants were asked to read the instruction page and then answer the questions. Whilst this was taking place, the parents/guardians were asked to write down the postal address for posting the questionnaire two weeks later. The researcher asked them to answer the questionnaire again and post it back in a prepaid addressed envelope to the provided address. Both parent/caregiver and participant were informed that it was crucial to receive the second response in order for the researcher to send the reimbursement to their home address. For each of the participants the posted questionnaire was marked with an identification number which was linked to the first questionnaire. This procedure ensured the questionnaire of each person on both occasions could be analysed anonymously and separately, without confusion.

4.4 Results and Findings of Questionnaire Development on ERQoL

4.4.1 Item Generation and Initial Item Reduction

The initial step was the generation of items for the questions from the qualitative data. The qualitative transcripts from the study were used for generating the items for the questions. Framework analysis was performed on the data and an analytical framework or index constructed which was used as a pool for the questions generation. According to the analytical framework, 8 categories were defined with various related subcategories. The extracted framework from the qualitative data are summarised in table (4.2),

Table 4.2 The extracted framework from the qualitative data

Themes	Sub-themes						
Functional difficulties	Difficulties in chewing	Difficulties in biting	Difficulties in swallowing	Cannot eat food properly			
Influence of time	Before starting the treatment	At the beginning of the treatment	After a week later	After a few months	Activation of the appliance		
Influence of the venue of eating	At School	At a restaurant	At home				
Influence of different kind of the appliances	Physical nature of the appliances	Demand of each specific appliance					
Influence of the instruction by the orthodontist	Insisting on restricting oral hygiene measure/continuous brushing	Dietary instruction	Preservation of the appliance				
Change in the way of eating	Eating speed	Meal number and meal change	Chopping hard foods	Having a softer diet	Amount of eating food	Tastes change	Having either positive or negative views on the changes
Influence of surrounding people	Effect of family	Effect of friends	Effect of school mate	Someone with brace			
Influence of certain type of food and drinks	Hard and chewy food	Sticky food	Soft diet	Fizzy, cold, hot and coloured drinks			

The initial pool aimed to be general and to include most of the issues that were covered by the analytical framework. The questionnaire was composed of 45 questions which were categorised under three broad domains *functional ability to eat, problems due to social factors and emotional and psychological aspects*. The domains of the first pool of the questionnaire also attempted to reflect the WHO definition and include all aspects of QoL i.e. functional, social, psychological and emotional categories. Due to the interrelation between the psychological and emotional subjects (Lazarus, 1998) and the fact that this trend was reflected in the analytical framework, both subjects were categorised under one domain. As such, the initial questions were finally categorised under three main domains: functional; social; emotional and psychological.

The items were then developed into a question with the hope of preserving originality or at least the content or the idea of the words as far as possible (Table 4.3). For some of the questions it was possible to preserve the main word of the questions such as *biting, chewing, got used to it*, while for some other questions it was difficult to derive it from original wording but the idea and simplicity of the questions were taken in consideration. This notion was also considered for the response options and where possible, related response options derived from the participant's words were used. These mostly included words commonly used by the patients, such as *difficult, uncomfortable, embarrassed, slow, taste....* Therefore, several types of response scale were considered to be included and applied according to the logic of the questions.

Table 4.3 An example of using the participant words in the questions.

Patients quotes	Derived questions
<i>“First couple of days and you might feel a bit uncomfortable, but then you just get used to them cos like three of my friends already had braces.” FF05</i>	After you got used to your brace, how do you find eating?
<i>“Like you had to chew in your mouth, but you couldn't chew and the food just all goes in the middle and you could not chew at all.”</i>	When eating with your brace, how do you find chewing foods?
<i>“I had time to just eat at my pace where at school you've like a set time but also you want to keep up with your friends you don't want to be like sitting there by yourself like trying to finish off.” FRE01</i>	How do you feel when eating with your brace when not in your own home? (For example, at school, restaurant, friend's home.....)
<i>“Your teeth when you are biting and that I don't know what type of feeling it is just hurt.” FRE01</i>	When eating with your brace, how do you find biting foods?
<i>“Cos there is lot of people there and you don't want like slop or anything.” MTB01</i>	How do you feel when eating with your brace in presence of a people you don't know?

The first domain *functional ability to eat* consisted of 16 questions (Table 4.4) about the functional difficulties according to the time of the placement of the appliance, different functional difficulties such as biting, chewing and swallowing. In addition this domain included questions about the eating difficulties in relation to the type of the appliances and the type of foods and drinks. The majority of rating scale was VAS, 2 Likert scale, 2 MCQ and 2 text only questions.

The second domain *problems due to social factors* was about the social issues associated with eating during the course of orthodontic treatment. This domain consisted of 15 questions with different scale of measurements. Six were Likert scale, 3 MCQ, 3 text only, 2 VAS and 1 Yes/No question (Table 4.5). The core of the questions mostly concentrated on the influence of the

surrounding people such as family and friends and the venue of eating such as home, school and other places.

The third domain *emotional and psychological aspect* was about the emotional and psychological impact of eating with orthodontic appliances. It consisted of 14 questions and the questions asked the patients about their different feelings and self-perception about eating and eating enjoyment during the treatment time. The majority of the scales were the Likert scale, 3 text only, 1 VAS and yes/no question (Table 4.6)

For easier cross referencing of the questions in the tables provided below, the questions were numbered continuously regardless of domain boundaries.

4.4.2 Initial Pool of the Questionnaire Items according to the Analytical Framework from the Qualitative Data.

Table 4.4 First domain of the initial pool of the questions.

<i>1st Domain: Functional ability to eat</i>			
No.	Questions	Scale of measurement	Related Analytical Framework
1	Before getting your brace, did you think eating with a brace was going to be difficult?	VAS Easy-----Difficult	2.a Before starting the treatment
2	When you first got braces did eating become difficult?	VAS Easy-----Difficult	2.b At the beginning of the treatment
3	Have you felt that biting the foods is difficult when the brace is on?	VAS Easy-----Difficult	1.b. Difficulties in biting
4	Have you felt that chewing the foods is difficult when the brace is on?	VAS Easy-----Difficult	1.a. Difficulties in chewing
5	When you have a brace do you feel that eating is difficult because the food stick to it?	VAS Easy-----Difficult	8.c. Sticky food or stickiness of food
6	Have you felt that swallowing the foods is difficult when the brace is on?	VAS Easy-----Difficult	1.c. Difficulties in swallowing
7	Once you get used to your brace, have your eating returned normal, or still difficult?	VAS Easy-----Difficult	2.c After week later
8	Have you experienced difficulties with eating certain food?	Text only	8.Influence of certain type of food and drinks

9	During the treatment, have you reduced the amount that you eat?	VAS Same-----Reduced	6.e. Amount of eating food
10	Has your brace affected the speed of your eating?	VAS Same-----Slower	6.a. Eating speed
11	Do you think this change is good or not? Why?	Text only	6.g. Having either a positive or negative views on the changes
12	Do you think the brace has affected the flavour of your food?	Likert Scale*	6.f. Tastes change
13	Do you have any difficulties with drinking?	Likert Scale*	8. Influence of certain type of food and drinks
14	If you have difficulties, can you select which type of drink?	Multiple Choice Selection Hot or cold water Juice Cola Other.....	8. Influence of certain type of food and drinks
15	If you have experienced different type of appliances which of them are most likely to be difficult to eat with?	Multiple Choice Selection Fixed appliance Removable appliance Functional appliances Retainer	4. Influence of different kind of the appliances
16	Do you have any other comments about the effect of your brace on your eating experience?	Text Only	

Table 4.5 Second domain of the initial pool of the questions.

<i>2nd Domain: problems due to social factors</i>			
No.	Questions	Scale of measurement	Related Analytical Framework
17	Does your brace affect how comfortable when you are eating with other people?	VAS Comfortable-----Worry	7. Influence of surrounding people
18	If you are not, who are you most uncomfortable eating with?	Family member Friend Teacher People you do not know Other.....	7. Influence of surrounding people
19	Do you think it would be helpful if these people have more information about braces?	Text only	Influence of surrounding people
20	Are you happy to eat with your brace with your friends?	Likert Scale*	7.a Effect of friends
21	Why are you satisfied or dissatisfied with eating with your school mate?	Text only	7.c Effect of school mat
22	Do you get more confidence when you have a meal with someone's who wear brace too?	Likert Scale*	7.d Someone with brace

23	Have your family changed what they eat because of your brace?	VAS No changed-----changed	6.b Change in the way of eating/ meal change
24	Have you felt uncomfortable eating a meal out?	Likert Scale*	3. Influence of venue of eating
25	Can you circle the place where you unconformable during eating?	a. Home b. School c. Restaurant d. Friend's home e. Other.....	3. Influence of venue of eating
26	Have you ever rejected someone's eating offer because of your brace?	Yes/No	
27	If yeas, why?	Text only	/
28	Have your eating habit changed because of the advice of your orthodontist?	Likert Scale*	5.b Influence of the instruction from the orthodontist/ Dietary instruction
29	Do you follow the instructions that your orthodontist gave you about the eating?	Likert Scale*	5.b Insisting on restricting oral hygiene measure/ Dietary instruction
30	Do you change what you eat depending on whether you are able to brush your teeth afterward?	Likert Scale*	5. a Insisting on restricting oral hygiene measure/ Continuous brushing.

31	When you are at school, do you prefer?	packed lunch school dinner both of them none of them	3.aInfluence of venue of eating /At School
----	--	---	---

Table 4.6 Third domain of the initial pool of the questions.

<i>3rd Domain: Emotional and Psychological aspect</i>			
32	During the treatment have you wished to eat a certain food but you can't?	Likert Scale*	8. Influence of certain type of food and drinks
33	When you are with your family or friends, do you become upset when foods stick to the brace?	Likert Scale*	8.c Influence of certain type of food and drinks/ Sticky food
34	Have you ever thought about stopping your treatment because you cannot eat well?	Yeas/NO	1.d Cannot eat food properly
35	If yeas, when it was happened?	Text only	/
36	Have you worried about what other people are thinking when you are eating with your braces?	Likert Scale*	7. Influence of surrounding people
37	If you have worried, what have you worried about?	Text only	/
38	Do you feel confident to eat the same meal as your friends?	VAS Confident-----Unconfident	8.Influence of certain type of food and drinks

39	If you have or don't have such confident, how you deal with this situation?	Text Only	/
40	Do you prefer to eat alone when you have the brace?	Likert Scale*	Influence of surrounding people
41	When you get your brace off, what is the first thing you are going to eat?	Likert Scale*	2.d After finishing the treatment 8. Influence of certain type of food and drinks
42	Have you ever been hungry because of your brace?	Likert Scale*	
43	Are you concerned about the damage to your brace when you are eating?	Likert Scale*	5.c Preservation of the appliance
44	Can you eat healthy food with a brace on?	Likert Scale*	8. Influence of certain type of food and drinks
45	If you don't think so, where is the problem?		/

Tables 4.3 - 4.6 Show the initial questions formed according to the analytical framework based on the qualitative analysis. Each table contains the particular domain and the related questions, rating scales and related references on the analytical framework. Moreover it shows the deleted and modified questions at the research team level. It also presents the deleted, retained and modified questions.

Deleted, because of:



1. repetition
2. the idea presented in other questions



Just the question words changed (18 questions)



Question format and the rating scale changed (10 questions)

Not at all	slightly	moderately	Quite a bit	Greatly
0	1	2	3	4
*Likert scale for all of the questions				

4.4.3 Modification of the Initial Questionnaire

After the initial organization of the questions according to the qualitative analytical index by the researcher, the research team participated in the initial reduction and modification of the questionnaire. The research team consisted of the lead researcher (orthodontist), one further orthodontist, a qualitative researcher and an expert in nutrition.

During this stage 15 questions were deleted (Table 4.4-4.5) and the most common reason behind the deletion was repetition of the questions. Furthermore, some questions witnessed major change by significant modification of the wording and the rating scale of the questions. Whereas for some other questions only minor changes were performed, limited to modifying the format to a non-leading question. At the end of the initial reduction process the questionnaire was shortened to include 28 questions (Table 4.7-4.9).

The first phase of corrections concentrated on the common sense, relevancy, format and grammatical consideration of the questions. Furthermore the research team tried to reformat the questions to reflect clinical and nutritional considerations. The initial questions were revised in order to be easier to read, open and non-leading. With leading questions the participants may be directed to the answers Yes or No may be the most possible answers. For example, question 40 (Table 4.6) was considered a leading question and question 26 (Table 4.5) the answer was limited to only Yes or No options. Questions which contained the same idea or were a continuation of other questions were rewritten to form a single question. For instance 21, 24, 25 and 31 (Table 4.5) asked about the difficulties in eating outside home, including school, therefore all of these four questions were united into one question. Furthermore, it is important that each question contains only one item of information, avoiding double barrelled questions to assist the respondent. For example, question 33 (Table 4.6) contained several activities such as eating in front of family or friend and stickiness of food which may confuse children with respects to which question to answer or what information is required. Finally, those questions which contained broad and general information have been removed. The reason behind such type of question can be answered according to the general background information rather than topic of interest of the study. The example of such questions can be found in questions 44 and 42 (Table 4.6).

The questionnaire format and the scale for the measurement was not unique and one of the requirements of a good measure is to have a scale that can determine the differences, can be easily understood by the participants and can be interpreted and analysed systematically by the researcher. Therefore, it must be efficient and simple in detecting the burden or impact of ERQoL on a patient's life. VAS and Likert scale are the two most common scales that are used in most of

the health studies (Streiner *et al.*, 2015) and both ratings were considered in this study. As a result, after initial reduction of the questions by the research team two questionnaires were formulated with the same questions but different rating scales applied, one with a VAS and the other with a 5 point balanced Likert scale (Tables 4.6 - 4.9).

The topics of the domains of the questionnaire were also modified to simpler language to make them more comprehensible by children. For example, Functional ability to eat changed to eating with your brace. Moreover one new domain You and your Dentist (Orthodontist) was added to the questionnaire and any questions about the relationship of the patient with the orthodontist moved to this new domain (Tables 4.6 – 4.9). The domains tried to include the all QoL categories and different terms were used for the titles for e.g. Eating with your brace to include the functional difficulties and Eating enjoyment to include emotional and psychological questions. This should help the children to understand the meaning of the content rather than using broad scientific terms like functional or psychological aspects.

In order to receive more qualitative information about the ERQoL, a free text area was provided for every question in the questionnaire. At the end of this stage the modified questionnaire consisted of 28 questions. 26 questions contained a rating scale and the other 3 just had text only spaces which are regarded as qualitative questions (Tables 4.6 – 4.9). Free text spaces were provided for all the questions. After all of these changes the initial questionnaire passed to the next stage of development which was content validity.

4.4.4 Content Validity

In the content validity phase, of the 12 orthodontic consultants and trainees at the Newcastle University/Orthodontic Department participated. The initial questionnaire with both VAS and Likert rating scale was sent to them electronically. The aim was to receive comments and feedback from the panel in both qualitative and quantitative ways.

Almost all the questions were reported by the panel to be clear and at an appropriate level of understanding for the children. Whereas 2 questions were considered by most of the panel to be less relevant or at least the idea had already been covered by the other questions. Although all the questions were regarded as simple and clear, two of the panels members commented on those questions where the question words and rating scale labels were integrated (Table 4.9 and Table 4.10; Q16, Q20 and Q25-Q28). While the other panel members regarded these questions to be clear and the idea of the question can be easily grasped because “*when you read you read both*”.

In addition to that, the VAS was regarded to be more simple and easier to indicate their responses, particularly using the visual aids which can help them to quickly understand the idea of the

questions. By contrast the Likert scale was not welcomed in some of the questions particularly the questions in the last domain (Table 4.10) where panel members felt it was difficult to categorise responses into 5 point answer options.

The process of content validity is summarised in the tables (Tables 4.7 – 4.10) which give a detailed overview about the selection, removing or changing the questions. Also it gives the some idea regarding the appropriateness of the two selected rating scales by presenting tick or cross signs. Finally it gives some abbreviated comments from the panel about the questions and the rating scale especially for those questions which showed some controversy.

Table 4.7 First domain during content validity stage.

Eating with your brace								
	Questions	Clarity %	Relev. %	Rating Scale				Further comment
				VAS		Likert		
1	Before getting your brace, how did you think eating with a brace was going to be?	100	83	Difficult-----Easy	✓	Very difficult Difficult Normal Easy Very Easy	✓	For those who are at the end of the treatment may not remember.
2	When you first got your braces, how did you find eating?	100	100	Difficult-----Easy	✓	Very difficult Difficult Normal Easy Very Easy	✓	For those who are at the end of the treatment may not remember.
3	When eating with your brace, how do you find BITING foods?	100	100	Difficult-----Easy	✓	Very difficult Difficult Normal Easy Very Easy	✓	
4	When eating with your brace, how do you find CHEWING foods?	100	100	Difficult-----Easy	✓	Very difficult Difficult Normal	✓	

						Easy Very Easy		
5	When eating with your brace, how do you find SWALLOWING foods?	100	100	Difficult-----Easy	✓	Very difficult Difficult Normal Easy Very Easy	✓	
6	After you got used to your brace, how do you find eating?	100	100	Difficult-----Easy	✓	Very difficult Difficult Normal Easy Very Easy	✓	
7	Are there any <u>specific foods</u> you find difficult to eat with your brace?	100	92	Qualitative question				
8	With your brace, <u>how much food do you eat</u> compared with before you had your brace?	100	83	I eat less ----- I eat more food food	X	<i>I eat very less food</i> <i>I eat less food</i> <i>I eat the same</i> <i>I eat more food</i> <i>I eat too much food</i>	X	<ul style="list-style-type: none"> • 3 categories enough for the Likert scale • Eat more food may be not related to the appliances.
9	How long does it take you to eat with your brace, compared to when you didn't have it?	100	100	I eat ----- I eat	✓	<i>I eat very slowly</i> <i>I eat little bit slower</i>		Quicker and very quickly have the same meaning.

				slower	quicker		<i>I eat at the same speed</i> <i>I eat quicker</i> <i>I eat too very quickly</i>	X	
10	Since wearing your brace how does your <u>food taste</u> ?	100	100	worse taste ----- taste	Better taste	X	<i>Taste very bad</i> <i>Taste bad</i> <i>Taste the same</i> <i>Taste good</i> <i>Taste very good</i>	X	<ul style="list-style-type: none"> • 3 points enough for the Likert scale • Better taste or taste very good is not unlikely
11	When wearing your brace, are there any <u>specific drinks</u> that <u>you avoid</u> ?	100	92	Qualitative question					
	Do you have any other comments about the effect of your brace on eating or drinking?								

Table 4.8 Second domain during content validity stage.

You, your family and the people around you								
	Questions	Clarity %	Relev %	Rating Scale				Further comment
				VAS		Likert		
12	How do you feel when eating with your brace in front of your family?	100	100	Uncomfort-----comfort -able -able	✓	Very uncomfortable Uncomfortable Comfortable	X	It is difficult to differentiate between quite comfortable and very comfortable

						Quite Comfortable Very comfortable		
13	How do you feel when eating with your brace in front of your friends?	100	100	Uncomfort-----comfort -able -able	✓	Very uncomfortable Uncomfortable Comfortable Quite Comfortable Very comfortable	X	
14	How do you feel when eating with your brace in presence of a people you don't know?	100	100	Uncomfort-----comfort -able -able	✓	Very uncomfortable Uncomfortable Comfortable Quite Comfortable Very comfortable	X	
15	How do you feel when eating with your brace when not in your own home? (For example at school, restaurant, friend's home.....)	100	100	Uncomfort-----comfort -able -able	✓	Very uncomfortable Uncomfortable Comfortable Quite Comfortable Very comfortable	X	
16	Since wearing your brace do you accept invitations to meals, parties.....?	83	83	Less often more often than -----than before before	✓	<i>Much more often</i> <i>Slightly more often</i> <i>Same as before</i> <i>Slightly less often</i> <i>Much less often</i>	X	This occasion may not happen every time and it is not more often frequent 3 categories enough for the Likert scale

Table 4.9 Third domain during content validity stage.

You and your Dentist (Orthodontist)								
	Questions	Clarity %	Relev %	Rating Scale				comments from the panel
				VAS		Likert		
17	How helpful did you find the instructions your dentist gave you about eating with your brace?	100	100	Less-----very helpful	✓	Not helpful at all Less helpful Helpful Quite helpful Very helpful	X	It is difficult to differentiate between quite helpful and very helpful
18	Did the advices of your dentist make you change the foods you eat?	100	100	Always-----Never	✓	Very often Often Sometimes Rarely Never	✓	
19	How often do you avoid eating foods, if you are unable to brush your teeth/clean brace after meal?	100	100	Very often-----Never	✓	Very often Often Sometimes Rarely Never	✓	
20	Does eating with your brace make you want to.....? (VAS)	100	83	Totally continue stop -----to wear wearing brace	✓	Very often Often Sometimes	✓	The question is not quite relevant to the domain topics.

	Does eating with your brace make you want to stop wearing your brace? (Likert)			brace		Rarely Never		
21	If you were a dentist what advice would you give to your patients about eating with brace?	67	42	<i>Qualitative question</i>				Not quite relevant to ERQoL and the idea not clear enough

Table 4.10 fourth domain during content validity stage.

Enjoyment of food								
	Questions	Clarity %	Relev %	Rating Scale				Further comment
				VAS		Likert		
22	When wearing your brace, can you eat the foods you want to?	100	100	Never----- Always	✓	Very often Often Sometimes Rarely Never	✓	
23	How enjoyable is eating with your brace?	100	100	Not Enjoyable ----- Very enjoyable at all	✓	Not enjoyable at all Not enjoyable Same like before Enjoyable	✓	

						Very enjoyable		
24	Do you worry when eating/drinking with your brace?	100	100	Always-----Never	✓	Very often Often Sometimes Rarely Never	✓	
25	When you are eating with your brace do you.....? (VAS) When you are eating with your brace, do you worry about what other people are thinking? (Likert)	83	83	Worry about what other people think Don't care about other people think X		Worry all the time Worry most of time Worry Sometimes Worry less time Worry not at all	✓	long labels description for VAS
26	When you first got your brace was your eating.....?	100	42%	Totally Not Strange-----strange	✓	Totally strange Strange Sometimes Normal Not strange Not strange at all	✓	Not related to the food enjoyment
27	When you eat with your brace, do you feel.....?	100	83%	Very Not embarr-----embarr- -assed -assed	✓	Very embarrassed Embarrassed Normal Embarrassed sometime Not embarrassed at all	✓	

28	When you have your brace, do you.....?	100	83%	Eat alone----- other all time	Eat with all time	✓	Eat alone all time Eat alone usually Eat just like before Eat withother sometime Eat with other all time	✓	<ul style="list-style-type: none"> The question is not quite relevant to the domain topics The format of the question
	Please make any other comments about the eating with your brace?								

Table 4.7-4.10 Modified questionnaire for the content validity stage. It shows the questions and the two proposed rating scales (VAS and Likert scale). The tables contain the particular domain and the related question, two rating scales and the panel's views on the clarity and relevancy of the questions and their judgment about the both rating scale. The comments column contains the most apparent critic's views of some of the panel on those questions which they were uncertain about the question format, clarity relevancy and the rating scales. Finally the table shows the deleted and modified questions at the content validity level.



Retained without change



Retained but just the sequence changed



Completely deleted

4.4.5 The Outcome of the Content Validity Phase

The result of content validity phase confirmed that most of the questions are well formulated and the level of clarity and relevancy are very high. Furthermore this stage played an important role in determining the rating scale for the questionnaire.

The content validity stage provided clear views about the questions and the panel agreed that most of the questions were expressed correctly. However, two questions concerned the panel mostly because of their relevancy rather than the clarity (9, Q21 and Table 4.10, Q26). The first one asked the patient if they were a dentist how they would instruct the patient. However, this may be an overestimation of the child's ability and its relationship with the subject of ERQoL was not strong. The second question about how strange it was to eat after insertion of the brace was thought to be irrelevant to the domain topic (food enjoyment) and also regarded as a kind of repetition. As a result both of the questions were deleted completely from the questionnaire. On the other hand the panel also recommended to add one other question about the activation of the appliance because is highly related to ERQoL due to the initiation of the pain by applying renewed force onto the dentition. After discussion and revision with the research team this question was also added to the first domain in the questionnaire.

Table 4.11 Added question after the panel's suggestion.



The added Question	After your usual visits for tightening the brace what would happen to your eating?
The rating Scale	<div><div>Become difficult</div><div>0</div><div></div></div> <div><div>Remain easy</div><div>10</div><div></div></div>

Table 4.11 shows the added question and its rating scale after the panel's suggestion at content validity stage. This question was added to the first domain and ranked number 3.

VAS was regarded by the panel as the best rating scale for inclusion in the questionnaire because the panel thought that it would be more easily understood by the children and the visual aids at the anchor labels gives a child-friendly appearance to the questionnaire. To check this, five child orthodontic patients were asked by a member of the research team (SLR) which scale they preferred. After being shown a sample of the questions with both VAS and Likert scales they were asked to choose the rating scale they preferred. All the participants selected the VAS as a rating scale.

The final procedure in this stage was modifying the title of the domains. The panel only raised the idea and the details of the changes were performed at the research team level. The detail of the changes of the domains have been is summarised in Table 4.12.

Table 4.12 Modification of the domains titles.

A: Domain title before content validity	B: Domain title after content validity
Eating with your brace	From the start and afterwards
	Eating with your brace
	Changes that happened
You, your family and the people around you	Surrounding people and venue of eating
You and your dentist (orthodontist)	You and your dentist (orthodontist)
Enjoyment of food	Enjoyment of food

Table 4.12 shows modification of the domains titles after content validity stage. The first domain was divided into 3 domains and the second domain title was changed to include the venue of eating as well. However the last two domains remained without any change

4.4.6 Summary of the Changes Following the Content Validity Stage

1. Deleting two questions Q21 (9) and Q26 (Table 4.10).
2. Adding one question about the effect of activation on ERQoL (1)
3. Adding a domain about the time effect and the eating habit change and changing the title of the second domain (2).
4. Selecting the VAS as rating scale of the questionnaire
5. Changing the position and sequence of two questions 20 (Table 4.9) and 28 (Table 4.10).
6. Printing the questionnaire in a booklet format and using black font (appendix A).

4.4.7 The Readability of the Questionnaire

In order to confirm the readability of the questions before the face validity stage with the children, the modified questionnaire after content validity stage was examined using the Flesch Reading Ease score and Flesch-Kincaid Grade Level. This method calculates the readability of a text according to the number of sentences, syllables and words (Flesch, 1948). This was conducted in Microsoft Word and the readability statistics examined and the results summarised in the Table 4.13.

Table 4.13 The readability of the questions.

Counts		Average		Readability	
Words	357	Sentences/paragraph	1	Passive sentences	0%
Characters	1677	Words/sentence	11.6	Flesch Reading Ease	90.4
Sentence	32	Characters/word	4.1	Flesch-Kincaid Grade Level	3.5
Paragraph	32				

Table 4.13 the readability of the questions Shows the readability of the question after applying Flesch Reading Ease 90.4 and Flesch-Kincaid Grade Level test 3.5. It shows that the questions can be easily understood by 9.5 (6+3.5) year old children.

4.4.8 Face Validity

The next stage of the questionnaire development was the face validity test on the modified questionnaire developed following content validity. In this stage 15 participants out of 38 agreed to take part in the study which is equal to 40% of the approached informants. Nine were females and 6 were males and their age ranged between 11- 16 years. All of them were undergoing fixed orthodontic appliance treatment. The most common cause of refusal was the length of the

procedure which was reported in information sheet to be about 45 minutes and the most common explanation was a need to return promptly back to school.

It is important that this test is conducted with the respondents to determine the ability of the instrument to measure what it is proposed to measure. Although the researcher asked the participants to mark or skip the difficult or irrelevant questions all the participants answered all of the questions without skipping or marking any of the questions. Moreover the free text area was answered by all the participants.

The start and end times of the questionnaire answering were recorded for all 15 participants of face validity stage. This is to be sure that the duration of the time for answering the questions and adding free text answers is reasonable. The mean time for answering the questionnaire was 14.4 minutes (4.73 SD). The maximum time was 21 minutes with adding text in most of the free text area and the minimum time was 6 minutes by adding text only in 6 of the free text spaces. After participants finished the questionnaire a short qualitative interview was conducted to gain more in-depth information about the clarity, comprehension, relevancy and the look of the questionnaire.

4.4.9 Results of Qualitative Interviews of the Face Validity

All the 15 interviews were audio recorded and transcribed by the researcher. The topic guide was prepared prior to starting the interviews and had been revised by the research team (appendix E3). Qualitative data analysis for the face validity interviews were performed. Based on the qualitative findings, minor modifications were performed in the questionnaire.

**10MF* is an example of the coding system used for the face validity interviews by the participants in the face validity stage. The number represents the participants' study number, the first letter represents the gender of the participant and the second letter represent the type of the orthodontic appliance.

Regarding the appearance and design of the questionnaire, at start of the session two separate designs of the questionnaire were showed to the participants. One contained coloured visual aids and the other without these features. Most of the participants were happy with its looks and most of them selected the questionnaire that contained cartoon faces, clouds, and visual aids. The reason for such selection was simplicity and the child friendly appearance.

*"I think it is better to be there, better for younger people, child friendly." 10MF**

"Yeah, it is quite good including these cartoon faces make it more happier." 11MF

"Because it is more simple, it looks simple." 2MF

All the participants were asked about the first page or instruction page in regards to clarity and comprehension. All participants indicated its simplicity and they had no difficulties in understanding the points of how to answer the questions.

“.....Pretty simple and details.” 3FF

All the children were able to understand the meaning and the idea of the VAS what they have to do with this. Word anchors were clear and also helped some of them to indicate their answer on the line.

“It is just to show where do you stand or what do you want whether you are not comfortable or whether you are, that is a things.” 11MF

“To show where scale on the scale and where you felt about it”13MF.

Most of the participants agreed that almost all the questions reflect their experiences with the orthodontic appliances. However a few of them indicated that they have faced some of the situations, if not all of them. Whereas couple of informants indicated that they haven't experienced those difficulties which are present in the questionnaire.

“I think the questions seem to be quite relevant to the topic.”. 11MF

“.... I have had some of them.....not all of them.”

Regarding the level of understanding of the questions (words and language of the questions), all the participants informed us that the questions are in their level of understanding and they have no any problem in understanding the meaning of the questions or the idea of them. In addition to that all of them read the questions by themselves alone and none of them asked the researcher or the parents/guardians for clarification of the questions meaning.

“It is simple reading really and easily explained..” 2MF

“Mostly I looked to the words but the faces more difficult.... I mean more easier for maybe younger people.” 11MF

“Yeah, like to say how I felt because I have just looked at the face and then tell you which one I have.” 14FF

All the participants answered all the questions without skipping any of them. They put the answers correctly on the line in different positions, in other words not sticking to the extremes or the middle of line. Only a few participants added extra information in the majority of the free text areas (the clouds). In contrast most of them selectively added their notes to a few of the free text areas. The reason behind this action was the necessity of further explanation of those questions.

“For some of them like did you do the... I would sometime write like no or something but... and sometime I would have longer explanation but usually it was just right amount of space.”
1FF

“Some of them are don’t need elaborate more.”

“....Like just to specify the answer more, is like when you ask about contain foods I gave an example.” 8MF

All participants agreed that the questionnaire can be easily answered by other children of their age without any problem because of simplicity and relevancy of the questions.

“Yeah they all should, they are pretty easy questions.” 11MF

Finally, the majority of the participants were happy with the questions and they did not have any comments about adding or removing any particular questions. One of the participants suggested adding a question about stickiness of food with the brace, and two other participants suggested removing one of the free text areas (7 and Table 4.10) that ask for adding further comments about eating problems which was reported as repetition. Therefore the first one was removed and the second one kept which is located at the end of the questionnaire.

“Adding a question onsticking stuffs to my brace...” 6MF

“I think both have kind of same questions or may be kind of same answer” 9FF

*10MF is an example of the coding system for the qualitative interview in the face validity stage. 10 represent participant’s number, M represents the gender and the F represents the type of orthodontic appliance (fixed appliance).

Based on the recommendation from the face validity interviewee and after discussion with the research team a question was prepared about stickiness of food to the brace and this was inserted in the second domain, *eating with your brace* (Table 4.14) and (appendix A).

Table 4.14 The added question after face validity.


The added Question	When eating with your brace, how do you find a problem with foods or food particles STICKING to your brace?
The rating Scale	<p style="text-align: center;">Difficult Easy</p> <p style="text-align: center;">  </p> <p style="text-align: center;">0 10</p>

Table 4.12 shows the added question and its rating scale after participant's suggestion at face validity stage. This question added to the second domain (Eating with your brace) and ranked number 8.

4.4.10 The Outcomes of the Face Validity

The results of face validity assured the researcher that the children can follow the questions easily without having any difficulties in understanding the meaning and the idea of the questions. It was established that the words and the appearance of the questionnaire are child friendly and the visual aids also helped them in their decision. VAS scale is appropriate for this age of children and the notion of the VAS line is clear. In addition, all participants indicated their answer correctly as demonstrated in the instruction page. Therefore all questions were answered and no questions were skipped by the participants.

The participants confirmed that most of the questions are relevant their situation with their orthodontic appliance as well. The outcome of face validity testing was implemented on the questionnaire as detailed, so as to be ready next phase of questionnaire testing which was the reliability phase.

4.4.11 Summary of the Changes Implemented in the Face Validity Stage

1. Adding a question about stickiness of food with appliance (Table 4.14).
2. Removing a question with free text area asking for further comment on eating difficulties (Table 4.7).

4.4.12 Reliability

At this stage the questionnaire consisted of 28 questions, 26 questions with VAS and the remaining 2 without this scale (appendix A). The reliability test included test re-test reliability and internal consistency for the 26 scaled questions which were analysed quantitatively by using SPSS. The internal consistency was examined using Cronbach's Alpha for each domain. The stability of the questionnaire was tested using test re-test reliability with a paired t-test for normally distributed data and Wilcoxon signed-rank test for not normally distributed data.

The percentage of the acceptance increased in the second phase of the study mostly due to the amendment of the estimated time required to answer the questions to 15 minutes in the information sheet and offering a £25 voucher reimbursement as a thanks for their participation. Therefore 30 patients out of 47 approached participants (64%) showed their willingness to participate in the study (Table 4.15). For the test-retest reliability 27 participants returned their complete second questionnaire on the first attempt after posting the questionnaire to their given home address. The remaining 3 did not return their questionnaires, therefore the researcher posted a reminder letter with the questionnaire for the second time. Fortunately, these remaining 3 questionnaires were received a few days later and 30 questionnaires were ready for reliability testing.

Table 4.15 Approached and accepted participants in the questionnaire development study.

Phases	Approached Participant	Agreed Participant	%
Face Validity	38	15	40%
Reliability	47	30	64%

a. Test Re-test Reliability

Each of the participants in the reliability phase answered the questionnaire twice, one at the Newcastle Dental Hospital and the second was posted to their home address two weeks later. The respondents in this test were 30 child orthodontic patients (11-16 years old) and all the participants indicated their answers on the VAS rating scale without skipping any of the question i.e. 0% non-response rate. Two statistical tests were used for analysing the test re test analysis. The first test was Intraclass Correlation Coefficient (ICC) at a domain level which showed good to excellent correlation between the two occasions. Only one domain (domain 1) showed moderate correlation (Table 4.16). The similarity can be seen using a broad look at the data at the two time points (Figure 4.3).

Table 4.16 ICC at a domain level.

Intraclass Correlation Coefficient					
Domain No.	Domain name	Intraclass Correlation	95% Confidence Interval		Sig
			Lower Bound	Upper Bound	
Domain 1	From the start and afterwards	.614	.292	.803	P<0.001
Domain 2	Eating with your brace	.744	.463	.878	P<0.001
Domain 3	Changes that happened	.834	.652	.921	P<0.001
Domain 4	Surrounding people and venue of eating	.973	.943	.987	P<0.001
Domain 5	You and your dentist (orthodontist)	.738	.449	.875	P<0.001
Domain 6	Enjoyment of food	.912	.815	.958	P<0.001

Table 4.16 shows that the ICC of the first domain showed moderate correlation between the first and second administration of the questionnaire. The correlations $> 0.7-0.9$ can be regarded as satisfactory to strong correlations and $<0.7-0.5$ as moderate to weak correlations. The second and fifth domains ICC are satisfactory and the third, fourth and sixth domain ICC are excellent.

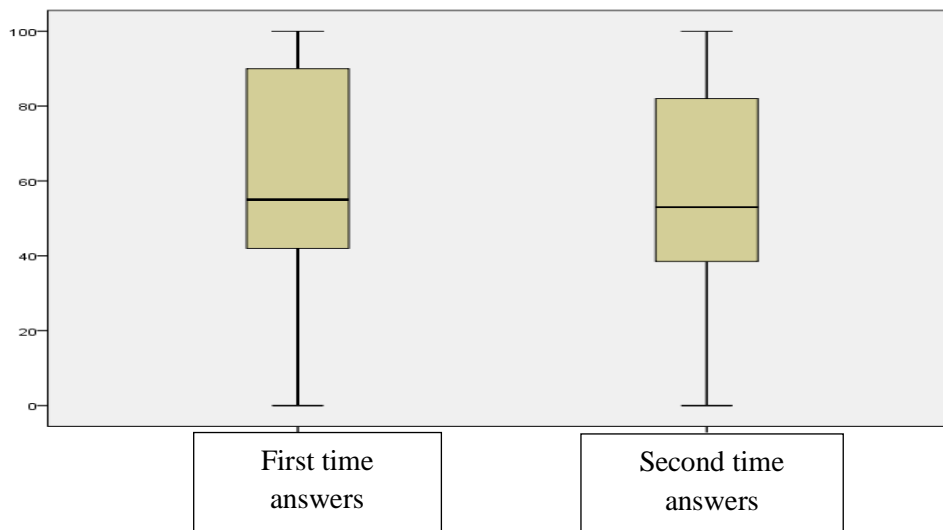


Figure 4.3 Boxplot of first and second time answers.

For each of the questions on both occasions a normality test was performed to determine the right test for comparing the response differences in both times. Shapiro and Wilk's test of normality is one of the most accurate methods to test the normality distribution of the data (Royston, 1982) and this test was used for such determination (Table 4.17). According to the statistic most of the data were not normally distributed (Table 4.17 – not-normally distributed data highlighted with blue box) in which the significance level / p-value < 0.05 , while for some other questions the significance

level $p > 0.05$ (Table 4.17/ green boxes). Therefore paired t-test was conducted for the 5 questions where on both occasions the data were normally distributed and for the rest the questions Wilcoxon signed-rank test conducted.

Table 4.17 Test of normality destitution of the data in both times.

Domains	Q.s	Tests of Normality time 1			Tests of Normality time 2		
		Shapiro-Wilk		Skewness Statistic	Shapiro-Wilk		Skewness Statistic
		Statistic	Sig.		Statistic	Sig.	
From the start and afterwards	Q1	.915	.020	1.070	.939	.083	.196
	Q2	.907	.013	.935	.968	.477	.586
	Q3	.967	.461	.396	.978	.760	.180
	Q4	.916	.021	.427	.813	.000	-1.285
Eating with your brace	Q5	.972	.596	-.016	.929	.045	-.535
	Q6	.732	.000	.427	.636	.000	-1.999
	Q7	.962	.341	-1.431	.945	.122	-.608
	Q8	.954	.211	.427	.947	.140	.674
	Q9	Qualitative question					
Changes that happened	Q10	.916	.021	-.355	.909	.014	-.008
	Q11	.676	.000	.427	.858	.001	1.644
	Q12	Qualitative question					
	Q13	.751	.000	.239	.774	.000	1.689
Surrounding people and venue of eating	Q14	.822	.000	.427	.815	.000	-.709
	Q15	.878	.002	-.966	.876	.002	-.046
	Q16	.864	.001	.427	.855	.001	-.393
	Q17	.890	.005	-.559	.901	.009	-.163

	Q18	.906	.012	.427	.882	.003	.185
	Q19	.865	.001	-.354	.791	.000	-.766
	Q20	.787	.000	.427	.869	.002	.322
You and your dentist (orthodontist)	Q21	.854	.001	-.110	.821	.000	-1.177
	Q22	.910	.015	.427	.947	.144	.390
	Q23	.888	.004	.093	.967	.472	.171
Enjoyment of food	Q24	.961	.324	.427	.946	.135	-.252
	Q25	.926	.038	-.573	.935	.066	.366
	Q26	.900	.008	.427	.929	.045	-.124
	Q27	.951	.184	1.370	.900	.009	.453
	Q28	.916	.022	.427	.837	.000	-.824

The normality test using Shapiro-Wilk for determining the normality distribution of the data at $p > 0.05$. This test used for each questions indicated most of the data were not normally distributed (blue coloured boxes)

Table 4.18 Paired t-test for the normally distributed data at both time 1 and time 2.

Qs in both time	Mean	Std. Deviation	t	Sig. (2-tailed)
Q3	8.200	22.754	1.974	.058
Q5	6.667	25.240	1.447	.159
Q7	5.833	24.740	1.291	.207
Q8	-.967	22.403	-.236	.815
Q24	6.800	19.963	1.866	.072

Paired t-test for the normally distributed data to determine the stability of question answers at two different time points with the same participants at $p > 0.05$. In this table all questions showed no statistically significant difference between the two times of administration.

Table 4.19 Wilcoxon signed-rank test statistic for not normally distributed data in both time 1 and time 2.

Qs in both time	Ranks	Sum of Ranks	Z	Asymp. Sig. (2-tailed)
Q1	Negative Ranks	307.50	-1.544b	.123
	Positive Ranks	157.50		
Q2	Negative Ranks	239.50	-1.214b	.225
	Positive Ranks	138.50		
Q4	Negative Ranks	282.00	-3.774b	.000
	Positive Ranks	18.00		
Q6	Negative Ranks	165.00	-2.819b	.005
	Positive Ranks	25.00		
Q10	Negative Ranks	217.00	-.320b	.749
	Positive Ranks	189.00		
Q11	Negative Ranks	177.00	-.880c	.379
	Positive Ranks	258.00		
Q13	Negative Ranks	178.50	-.076b	.939
	Positive Ranks	172.50		
Q14	Negative Ranks	88.00	-.282c	.778
	Positive Ranks	102.00		
Q15	Negative Ranks	69.00	-1.869c	.062
	Positive Ranks	184.00		
Q16	Negative Ranks	211.50	-2.240b	.025
	Positive Ranks	64.50		
Q17	Negative Ranks	198.00	-1.374b	.170
	Positive Ranks	102.00		
Q18	Negative Ranks	219.50	-1.118b	.263
	Positive Ranks	131.50		
Q19	Negative Ranks	179.00	-1.708b	.088
	Positive Ranks	74.00		
Q20	Negative Ranks	165.00	-.822b	.411
	Positive Ranks	111.00		
Q21	Negative Ranks	127.00	-1.808b	.071
	Positive Ranks	44.00		
Q22	Negative Ranks	158.50	-1.014c	.311
	Positive Ranks	247.50		
Q23	Negative Ranks	236.50	-.411b	.681
	Positive Ranks	198.50		
Q25	Negative Ranks	210.00	-.877b	.381
	Positive Ranks	141.00		
Q26	Negative Ranks	200.50	-1.023b	.306
	Positive Ranks	124.50		
Q27	Negative Ranks	10.75	-.380b	.704
	Positive Ranks	13.94		
Q28	Negative Ranks	216.50	-1.901b	.057
	Positive Ranks	83.50		

Wilcoxon signed-rank test which is a non-parametric test used for determining the stability of the questions which are not normally distributed between the two time points at $p > 0.05$. It showed

that for all of the questions except Q4 and Q6 (coloured boxes) no statistically significant difference was found between the answers of each of the two questionnaire administrations.

According to the results of both paired t-test and Wilcoxon signed-rank test 24 out of 26 questions were greater than the significance level of $p > 0.05$ which indicated no statistical significant difference between the two occasions (Table 4.18 and

Table 4.19). In other words, the questions appeared to perform similarly on both occasions across the two week interval. This result further confirmed the ICC (Table 4.16) in which the correlation between the domains were satisfactory except the first domain which showed moderate correlation. The moderate correlation of the first domain may be due to the presence of Question 4 which showed a highly significant difference between the first and second time answers (Table 4.17 - red box). This question was a time related question and asked when the patient adapted to the situation of the orthodontic appliances. The participants may get confused about the idea of the question whether it was asking when they coped with the appliance or when their eating returned to normal after a period of adaptation.

The next question which was showing a significant difference between the two times of questionnaire administrations was Question 6 ($p = 0.005$). This question is a straightforward question about the difficulty of swallowing during the treatment time, which is one of the common difficulties particularly at the start of the treatment. Therefore retaining or removing this question should be considered carefully.

b. Internal Consistency

Cronbach's alpha used to determine the internal consistency of the questionnaire. On the questionnaire level the internal consistency was excellent (0.93). This high correlation is mainly due to the number of the items i.e. 26 questions. However, when considered at a domain level the scenario changed and the first and the fifth domains showed relatively low correlation (Table 4.20) and the second domain showed only moderate correlation. Whereas the other domains showed satisfactory and excellent correlation ranging from 0.78 to 0.908.

Table 4.20 Internal consistency reliability on the domain level.

Domains	Cronbach's Alpha	N of Items
First Domain: From the start and afterwards	0.460	4
Second Domain: Eating with your brace	0.654	4
Third Domain: Changes that happened	0.780	3
Four Domain: Surrounding people and venue of eating	0.908	7
Fifth Domain: you and your orthodontist	0.562	3
Sixth Domain: Enjoyment of food	0.876	5

The first domain showed the lowest score for internal consistency. This was probably because this domain is mostly time related and asked questions which may be difficult for some of the patients to recall particularly when they are at the end of treatment. The question most susceptible to change in this domain was Question 1 which therefore had to be removed. By this action the correlation of the domain improved to 0.544 which may be regarded as moderate correlation (Table 4.21).

Table 4.21 Cronbach's Alpha of first domain following deletion of items.

First Domain: From the start and afterwards	Cronbach's Alpha if Item Deleted
Q1. Before getting your brace, how did you think eating with a brace was going to be?	.544
Q2. When you first got your braces, how did you find eating?	.097
Q3. After your usual visits for tightening the brace what would happen to your eating?	.291
Q.4 After you got used to your brace, how do you find eating?	.187

4.4.13 Analysis of the Qualitative Questions

This analysis relates to the qualitative questions (Question 9 and Question 11) which were without a measurement scale. Two spaces were provided for each of the questions one for adding the name of specific foods or drinks and the other space for adding the further information. The name of the

specific foods and drinks was added to the first space by 85% of the participants for specific foods and nearly the same value for the specific drinks (

Table 4.22). In this analysis the answers of each question in both times was investigated to establish what information was repeated on both occasions. Those answers that had the same content and idea were regarded as consistent information. For the question about indicating a specific food which they avoided during their orthodontic treatment, the answers were mostly around hard and chewy foods such as breads, apple, toffee and meats. The second qualitative question was about the avoiding of drinks after insertion of their orthodontic appliances. The most common answers both times were fizzy drinks and high sugar content drinks. Approximately 75% of respondents added answers and these had nearly the same information in both of the qualitative questions.

Table 4.22 Statistics and analysis of the two qualitative questions (Question 9 and Question11).

Questions		First time	Second time	Most common answer/reasons	Less common answers/reasons
Q9. Specific foods	Provided Answer	90%	80%	Apple Bread	Sweet Corns
	Consistency	80%		toffee meats	Crisps Pasta
	Free Text added	77%	73%	Stuck to the brace Hard to bite Chewy	Damage to the brace Pain (hurt) Dentist told
Q.11 Specific drinks	Provided Answer	84%	87%	Fizzy drink fizzy pop, sugar drink	energy drink tea
	Consistency	70%			
	Free Text added	57%	67%	Damage to teeth and brace Dentist told	Sugar content Stain the teeth or brace

4.4.14 Free Text Area

This area was provided for every question to receive more in depth information about the answer indicated on the VAS or expand the answers with the two qualitative questions. Generally, in both reliability and face validity stages 46% of the questions were accompanied by a text explanation. On the other hand for over half of the questions text was not added into the free text area and this was left blank without adding any comment (Figure 4.4). Most of the added text was just a confirmation for the provided answer while in some other questions more in-depth information was provided with a reasonable justification for the indicated answers. The mean number textual explanations given was about 12 per questionnaire in both stages although this was slightly higher in the face validity stage (14.5) compared to the reliability stage (10.2) (Table 4.23).

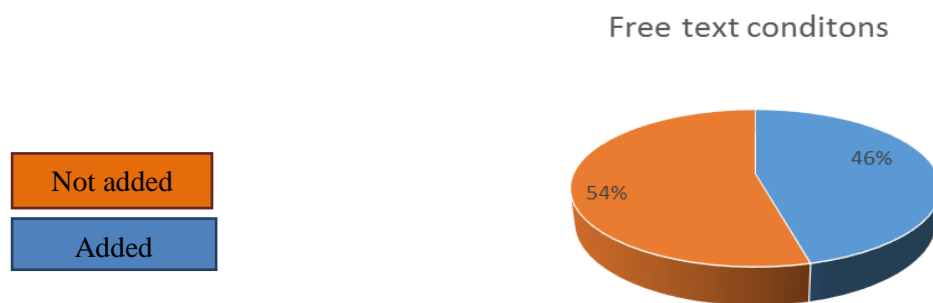


Figure 4.4 the percentage of added and not added text in all stages (face validity and reliability)

Table 4.23 Statistics of the added texts

Stages	Mean	SD	Percentage
Face validity	14.5	6.7	49%
Reliability	10.2	12.2	42%

During the face validity stage 14.5 text added per a questionnaire while in the reliability stage the number of added response reduced to 10.2 added text in the free text area for each questionnaire. Added answers in the free text area (42%) were also analysed for consistency between the answers in both occasions during the test re-test stage (Table 4.24).

For this analysis, the free text comments were divided into three categories as follows:

1. Text added on both occasions with the same content or at least the same idea or meaning.

2. Text added on both occasions but with different content, ideas or meaning.
3. Text added on only one of the occasions either first or second.

Table 4.24 Consistency analysis of the added texts.

Consistency analysis of the added texts	Percentage	Consistency decision
Adding same texts (content, idea or meaning)	26%	Consistent
Adding different texts (content, idea or meaning)	6%	Not Consistent
Only adding texts in one of the occasions	10%	Not Consistent

Most of the answers written in the free text area were consistent between both of the times. The criteria for deciding the consistency were inclusion of the same phrase, word or idea and meanings which was 26 % of all free text responses. Whereas 16 % of the answers were inconsistent either due to adding a text which contradicted the idea or meanings of the first occasions or adding text only one of the occasions (Table 4.23).

4.4.15 Some Examples of the Added Texts

As mentioned earlier most of the added texts in the free area can be interpreted as confirmation of their given answers alongside some in-depth information received from some participants in both face validity and reliability stages. Most of these answers were based around the different issues of ERQoL and can be regarded as a confirmation or summary of the qualitative findings. For more clarification some examples are listed below.

*214 is an example of the coding system for the questionnaire answer by the participants in the test re-test reliability stage. First number (2) represents the first or second occasion. The other number (14) represents the participants study number.

*FV3 is an example of the coding system for the questionnaire answer by the participants in the face validity stage. FV represent face validity and the number represents the participants' number.

Q2. When you **first got your braces**, how did you find eating?

*"It was harder to eat and hurt for the first week." 214**

"I thought it was going to be easy but I found it very difficult. 212

"It was hard at first but I got used to it." 213

"Some food were difficult to eat unless they are soft because my teeth still hurt from getting brace fitted." 225

Q8. When eating with your brace, how do you find a problem with foods or food particles **STICKING** to your brace?

"Very difficult and embarrassing." 121

"A bit annoying but ok when you brush your teeth." 214

"I found very frustrating and happens quite often. Sometimes it is easy to get out other not so easy."126

Q10. How long does it take you to eat with your brace, compared to when you didn't have it?

"It takes longer to break up the food." 121

"At first I ate quite slowly but now I eat normal to what I did without the brace." 213

"It takes me longer because I have to eat." 212

"Takes longer to properly chew and get food unstuck." 29

Q15. How do you feel when eating with your brace in front of your friends?

"I feel the people are watching because the food gets stuck." 110

"Lots of my friend have a brace so I don't feel too uncomfortable." 213

"The brace are hard to see most of times and my friends don't mind." 127

"Used to it now and most of my friends have them." 228

"I mostly comfortable but try to hide it if I have food in my brace." 221

Q19. When you are eating with your brace do you.....?

"I worry if I get food on my brace and if people see." 126

"After eating I must rinse my mouth to unstick food, that is only problem."121

"I worry that they are laughing or judging me."222

Q22. Did the advice of **your dentist** make you change the foods you eat?

"Sometimes I eat food that my dentist tells me not to, because of my friends." 220

"So I don't break my brace." 14

"Not really, I ate the same. I was a bit cautious after first getting my brace." FV1

Q24. When wearing your brace, can you eat the foods you want to?

*"Doesn't affect my diet however I choose to avoid foods like apple however I have not stopped eating them completely." FV3**

"I tend to stay away from food that bad for brace but I still eat them." 227

"Some food like rice can be an annoying so I limit that a bit." FV4

Q29. Please make any other comments about eating with your brace?

"Sometimes when I get my brace tightened it hurts to eat normal food." 227

"I found it very hard when had my fixed pallet because food stick to it and took me longer to it." 224

"I fear that I get a lot of food in my braces at school, where I can't brush my teeth to get out." 22

4.4.16 Interpretation of the Score

The questionnaire aims to detect any change in ERQoL during the course of the treatment. The developed questions scored the differences in difficulties and problems from 0 to 10 which is converted during the analysis from 0 to 100 in a millimetre scale rather than centimetre during the measurement and analysis. This provides a much more precise mathematical description of the records. The VAS rating scale was arranged in a way that the 0 indicates the largest changes or most negative perceptions of ERQoL. In some questions this negativity or these changes can be seen directly from the anchor labels, for example, uncomfortable, difficult, worry and stop wearing braces. Whereas in some other questions the notion of changes or negative perceptions can be found indirectly through the idea of the question. Therefore the 0 numbers were inserted to interpret these conditions and the visual aid in these extremes tried to reflect such perceptions by inserting sad or uncomfortable expressions on cartoon faces.

On the other hand the number 10 was inserted at the far end of the scale which represents the most positive outcome or no changes in perception of the ERQoL. The visual aids also at this end tried to reflect such notions by providing a happy face expression. Therefore, any score as close as to the 0 is meant that the related situation of ERQoL is affected by the orthodontic treatment, while

the score closer to 10 represents minimum or no change with wearing the orthodontic appliances during the course of the treatment.

The scores reported in the questionnaire (Table 4.27) indicated that ERQoL was affected to various degrees. Eating related difficulties at the start of the treatment received the lowest score of 34 (Q2) which indicated the greatest problems at this time. In contrast most of the participants rated the clarity of the eating related instruction by the orthodontist highly at 88.5 (Q21). However most of the mean scores were around the mid-point (Table 4.27). Furthermore, The mean score on both occasions of questionnaire testing also showed the impact of orthodontic treatment on that the ERQoL (Table 4.26).

The mean of the first time was 5.8 (SD 1.4) while the second time was 6.0 (SD 1.5), which indicated nearly no change and non-statistical difference between this score at $p \leq 0.05$ (Table 4.25). This is likely to be related to the short time interval between the two observations, which is used for determining the stability of the questions rather than measuring the differences in ERQoL. The same result was also observed at the domain level, where scores were generally around the midpoint of the VAS line on both occasions (Table 4.26). In order to use this questionnaire to determine a change in ERQoL it is essential to perform the observations over a long interval of time, particularly at the start, middle and end of the treatment to explore the effect of the time and treatment progression on the ERQoL. This could also be implemented on participants of different ages (adults and children) and genders (male and female) and different type of orthodontic appliances to determine the impact of these factors on the ERQoL.

Table 4.25 The mean of the score of the each domain in both times.

Domains	Time 1 Mean score	Time 2 Mean score
From the start and afterwards	4.6	5.2
Eating with your brace	6.1	6.3
Changes that happened	4.8	4.9
Surrounding people and venue of eating	6.5	6.6
You and your dentist (orthodontist)	6.3	6.4
Enjoyment of food	5.9	5.9

Table 4.26 Paired t test of the mean of the questions in both times.

Qs in both time	Mean	Std. Deviation	T	Sig. (2-tailed)
Time 1 and Time 2	-.115	.326	-1.806	.083

Table 4.27 Descriptive pilot data on ERQoL in child orthodontic patients in the UK

Domains	Related Health Domain	Questions	Mean	Median	Mode	SD	Range
From the start and afterwards	Functional	Q1	33.97	29.5	32	24.34	100
		Q2	34	28	15	22.938	82
		Q3	35.77	31.5	23 ^a	21.152	80
		Q4	80.5	82	100	17.264	68
Eating with your brace	Functional	Q5	55.23	54.5	47 ^a	25.628	94
		Q6	82.37	97.5	100	25.754	90
		Q7	60.43	58.5	50	27.215	100
		Q8	39.43	45	0 ^a	21.167	77
		Q9	Qualitative question				
Changes that happened	Functional	Q10	44.57	48.5	53	15.584	77
		Q11	52.93	52	49	14.239	100
		Q12	Qualitative question				
		Q13	47.53	50	50	14.906	100
Surrounding people and venue of eating	Social	Q14	79.07	89.5	100	24.209	78
		Q15	65.3	72.5	100	33.82	100
		Q16	61.17	74.5	100	36.218	100
		Q17	60.8	52	100	32.89	100
		Q18	65.77	54.5	100	24.462	86
		Q19	68.07	72	100	32.217	100
		Q20	54.5	51	50	16.414	80
You and your dentist (orthodontist)	Socio-Functional	Q21	85.87	88.5	100	14.093	40
		Q22	52.77	49	100	27.086	87

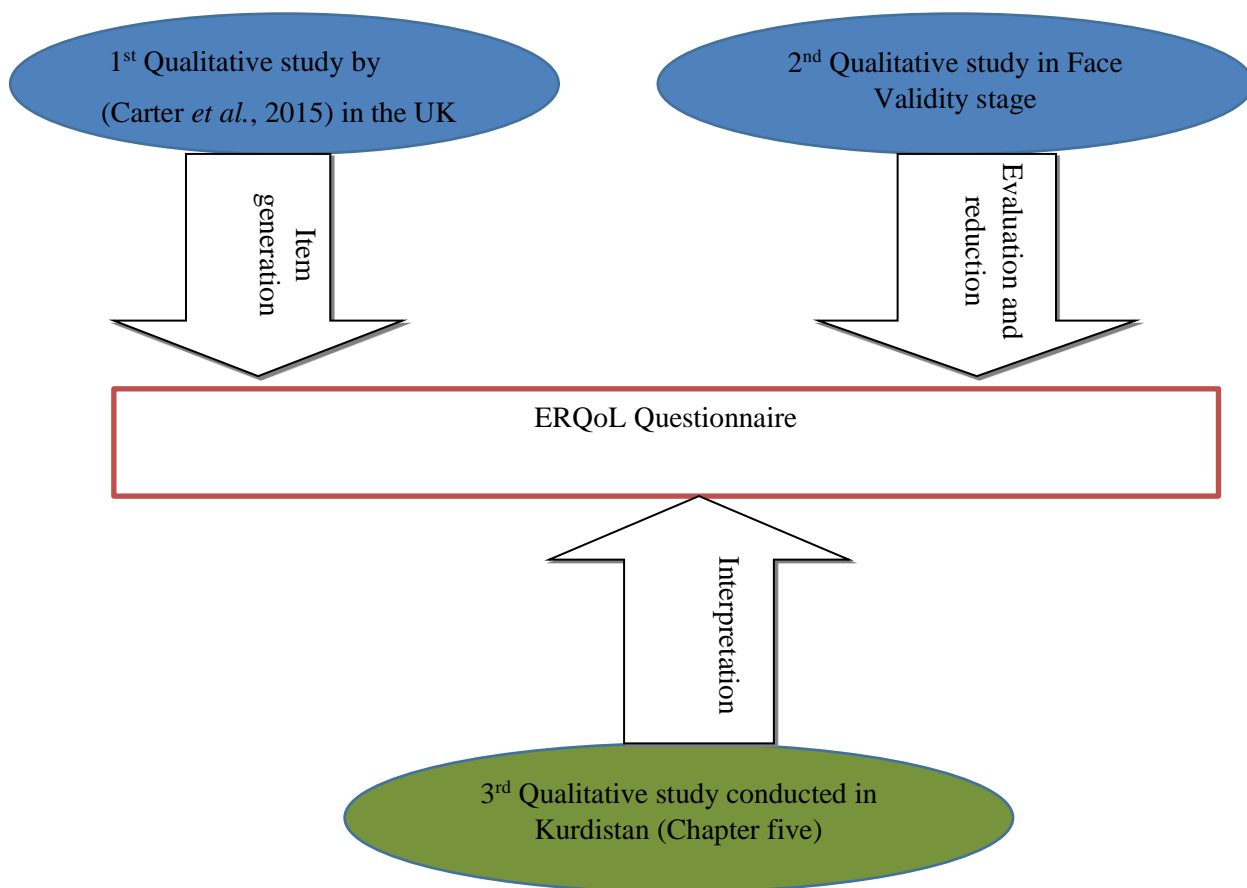
		Q23	51	44	100	24.314	87
Enjoyment of food	Psycho-Emotional	Q24	62.27	61	100	24.537	87
		Q25	47.63	49	48 ^a	19.711	100
		Q26	58.23	47	100	30.125	100
		Q27	55.97	54	50	26.192	100
		Q28	61.83	54.5	100	30.077	100

4.5 Discussion

4.5.1 Introduction

. Qualitative studies are mostly used to make the research more patient-based by extracting information directly from patient experiences rather than purely from the clinical perspective of the orthodontists. In the current study different qualitative methods were utilised to develop the ERQoL questionnaire to include as far as possible patients perceptions in both generation, evaluation, reduction and interpretation of the questions. The first example of this was the previously conducted study by Carter *et al.* (2015) in the UK, which was used for item generation for the ERQoL questionnaire. The second qualitative method was performed during the face validity stage to ensure that the generated questions could be understood by the orthodontic patients and allow them to evaluate the relevancy and clarity of the questions. Finally, a separate qualitative study was performed in Kurdistan of Iraq which then used to aid interpretation of quantitative findings from the second study (this will be discussed in the next chapter), (Figure 4.5). Mallinson (2002) reported, sometimes quantitative methods for determining the validity of a health instrument may fail because it relies mainly on the quantitative psychometric methods without returning back to the opinions of patients.

Figure 4.5 Using three different qualitative studies for developing the ERQoL measure to ensure patient centeredness.



If the respondents are children, the questionnaire needs more attention than a questionnaire for adults, because the level of understanding and cognitive abilities of adults and children are quite different. To make the questionnaire easy to read and understood by the children, some extra effort may be necessary. First of all, phrasing and arrangement of the questions such as wording and ordering the questions may increase the level of understanding. Secondly, using visual aids, different colours and writing with special font and spacing may increase the attractiveness of the questionnaire. As a result, for the child respondents it is important to develop a questionnaire directed to that particular age to prevent child position bias (a tendency to answer the first questions), acquiescence bias (a tendency to agree with a statement all the time) and avoiding negatively worded questions (Pantell and Lewis, 1987). This problem may arise when psychometric standards of the questionnaire are not compatible with children's responses (Jokovic *et al.*, 2002). Understanding patient experiences of certain types of treatment and interventions becomes central in understanding health outcomes and treatment needs of patients and revision of the health system by health policy makers (Liu *et al.*, 2009). Different OHRQoL measures have been introduced to capture orthodontic satisfaction and perceptions such as CPQ, OHIP and ODIP. The current study also attempted to explore patient's perceptions of eating related difficulties

during the course of orthodontic treatment to show the ERQoL impact of this treatment. Most of the available OHRQoL studies indicate that eating is one of those difficulties that the patients will face during orthodontic treatment and existing OHRQoL measures cover this issue using only a couple of a generic questions, or not at all, which cannot reveal the real picture of the eating related difficulties. The information from this study can provide more insight on expectations about eating difficulties that patients may experience and better prepare them about how to face these difficulties through improved dietary instruction delivered by orthodontists. Moreover, based on the realistic information from the patient, the quality of care during orthodontic treatment may be improved by increasing the patient's compliance with the treatment and commitment of the orthodontist in providing better quality of care based on the patient's reports (Zhou *et al.*, 2014).

4.5.2 Sample Size

It was not possible to undertake a formal sample size calculation for the two phases of the questionnaire development (face validity and reliability) and therefore the sample size recruited was based upon experience and previous studies. The face validity stage was a more qualitative phase, aiming to get more detailed information about the developed questions in an open discussion rather than relying on numerical ranking or statistics. The same strategies were used by Marshman *et al.* (2010) to evaluate questions in the short form of the CPQ11-14 (CPQ ISF-16). By interviewing only 10 participants they found that some questions in the questionnaire were irrelevant and there were some other conditions thought to be relevant but not included in CPQ ISF-16. In the current study, 15 orthodontic patients participated in the face validity and this number was found to be satisfactory in providing enough information about the relevancy of the questions and to ensure that the items made sense to the participants and this was a point where data saturation was reached.

In the reliability stage the internal consistency was measured using Cronbach's alpha, which is the most common measure employed to determine the reliability of an instrument. The exact sample size for determining the alpha correlation is controversial. Fleiss (1986) suggested that 10-25 participants are needed while (Nunnally and Bernstein, 1994) indicated a much higher number is required i.e. 300 or more. On the other hand, (Iacobucci and Duhachek, 2003) indicated that the alpha correlation is not sensitive to the sample size by itself and 50 participants can give very strong items correlations. On the other hand, the sample size should not be too small or too large because a sample size which is too small will produce a test with lack of power and wide confidence intervals while a large sample is a waste of resources and unethical (Bonett, 2002). In addition, alpha correlation does not depend on the sample size and it is not important in this regard and a stable result can be obtained even with a small sized sample (Ercan *et al.*, 2007). The sample

size required for establishing test-retest reliability is also not consistent in the literature and a standardised method for establishing this has not yet been established. In this study 30 patients were recruited to answer the questionnaire on two different occasions. Such a number has also been used in other dental studies such as (Cunningham *et al.*, 2000) who used 24 orthodontic patients after a relatively long interval which was 6 weeks after the first administration. Furthermore, (Kelly *et al.*, 2012) used 30 participants to determine the stability of a questionnaire about ERQoL in patients wearing different types of prostheses. Therefore, in this study 30 participants were proposed to participate in the reliability testing and this was found to be satisfactory in determining internal consistency and stability of the questionnaire between two different times.

Although Carter *et al.* (2015) extracted the raw qualitative data from patients with fixed, removable and functional appliances in the UK and the majority of the participants were children with fixed orthodontic appliances. Moreover during the development processes of the questionnaire in the UK in both face validity and reliability, all the participants were in fixed orthodontic therapy. Therefore the data mostly represents fixed orthodontic patients and the developed questionnaire should be applied to those patients in the UK. However the relevancy of the questionnaire to the other orthodontic patients and different geographical locations needs further work to assess its validity.

4.5.3 Layout and Rating Scale of the Questionnaire

The selected study group represented the majority of patients who receive NHS orthodontic treatment, and the methodology ensured that the questionnaire could be easily understood by this age group and was appropriate for capturing the experiences of a large range of orthodontic patients.

The questions were listed according to the commonality of the difficulties and simplicity of the questions to clarify the primary purpose of the questionnaire (McColl *et al.*, 2001; Dillman, 2007). For the same reason the functional domain was included at the beginning of the questionnaire. Here the questions about biting, chewing and swallowing, and stickiness of food were presented first because they are purely functional and almost all of the participants will have faced these problems. By giving participants the easiest question to answer at the beginning of the questionnaire may increase the response rate and can capture the attention of participants (McColl *et al.*, 2001; Taylor *et al.*, 2002; Bowling, 2009).

Too much information and congestion within the questionnaire was avoided because it has been demonstrated that a less crowded instrument with the use of appropriate spacing makes the questionnaire look better and leads to improved co-operation and fewer errors (Bradburn *et al.*,

2004). Therefore the questionnaire tried to provide enough space and a clear font to make it easy for the respondent to read and follow the questions. This was mostly to attract the participant's attention to the questionnaire and enhance the response rate. The use of green paper was chosen because research shows that questionnaires with different coloured paper other than the white paper may increase the response rate, particularly pink, green and blue paper (Fox *et al.*, 1988; Etter *et al.*, 2002). The visual aids in the VAS were also printed in colour to enhance attractiveness. Moreover applying Flesch Reading Ease 90.4 and Flesch-Kincaid Grade Level test 3.5.ensured the questions could be easily understood by 9.5 (6+3.5) years old children. As such, the look of the questionnaire and its language was reflected in the exceptional response rate; all the participant answered all the questions in both face validity and test re-test stages.

The face validity phase clearly indicated that participants preferred the VAS because of its simplicity. Natapoff (1978) indicated that it is important to use a scale that is compatible with the cognitive level and understanding of children. The content validity stage also supported use of the VAS indicating that the Likert scale was not applicable for some of the questions. This was mostly because it is difficult to have a fixed 5-point Likert scale for some of the questions and customised options had to be constructed for each of the questions or a group of related questions. This resulted in problems selecting the most appropriate options. For example for Q14 (Q1 in the fourth domain - see appendix A) '*How do you feel when eating with your brace in front of your family?*', the options presented were Very uncomfortable, Uncomfortable, Comfortable, Quite Comfortable and Very comfortable (Table 4.8). For this question, a 3 options Likert would have been enough, and participants might find selection of the appropriate answer confusing. Whereas for Q10 (Q1 in the third domain) '*How long does it take you to eat with your brace, compared to when you didn't have it?*' the 5-point answer option could be easily confused because children may not be able to understand the relative difference in speed and comprehend the difference between very slow and a little slower which are the first two options (Table 4.7). Therefore it is not thought applicable to limit the options to 5-points or 3-points in one questionnaire which could confuse participants and complicate the process of the analysis. This argument is also consistent with the findings of Osborne and Costello (2009) who concluded that the Likert scale with 9, 5 and 3 points should be used carefully with children particularly with the abstract concept. Osborne and Costello (2009) also indicated that children mostly prefer both extremes of the scale which is equivalent to yes/no format of scale for the children, whereas older children prefer the mid-point which is the point of uncertainty.

4.5.4 Decision on Inclusion and Exclusion of Items: Influence of Qualitative Data from UK and Kurdistan Child Populations

Zhang *et al.* (2007) indicated that most of the orthodontic patients anticipated QoL deterioration particularly functional limitation, with pain and the food restriction being the most noticeable examples. In the first domain of the developed questionnaire a question was included about the expectation of eating difficulties to give us information about patients' preparation or compliance before starting the treatment (appendix A). The question was formulated in simple language which stated *Before getting your brace, how did you think eating with a brace was going to be?* This was included as the first question, to preserve the chronological nature of the questions. However this question was highlighted as one which may be discarded during questionnaire testing procedures. The internal consistency of the first domain was low and the alpha correlation was 0.460 (Table 4.20) but after deletion of this question the internal consistency correlation was raised to 0.544 (Table 4.21) which can be regarded as an improvement of the consistency between the remaining questions of the first domain. This may be due to the nature of this question which asked the patients to give a virtual response, with their answer based on their memory rather than a real experience. Furthermore some of the patients questioned were in the middle or the end stages of their treatment so it may be difficult for them to recall this information. This question can be regarded as an important question which can be used as a reference point to compare with the eating difficulties at the start of the treatment and after adaptation.. However, this question could be retained in the questionnaire but not including it in the scoring i.e. it could stay in to act as a reference point but not contribute to the ERQoL score.

Adaptation of patients to the orthodontic appliances is a noticeable event and generally occurs within the first few months after insertion. This was one of the common themes that was discussed by participants in the qualitative studies, during the face validity interviews and in the free text comments (section 4.4.15). Sergl *et al.* (2000) also highlighted the adaptation of the patients to the orthodontic appliance conditions in terms of functional and social acceptance. Therefore in the questionnaire Q4 was dedicated to asking about eating after this period of adaptation had occurred. This question was also inserted in the time dependent domain (the first domain) of the questionnaire and the words "used to" were used to indicate adaptation to preserve the words of the patients in constructing the questions. The question '*After you got used to your brace, how do you find eating?*' with VAS anchors '*difficult*' and '*easy*' included. During the test re-test reliability phase, this question was found to have a significant difference between the two response times (

Table 4.19). This may be due to the time dependency of the question and difficulty recalling the information. However, this question was retained in the questionnaire because adaptation to the appliance is one of the obvious events that almost all the patients will see during the treatment, generally a few weeks after placement of the appliances. Therefore to preserve the patient's perception in the questionnaire it was thought necessary to include this question, because in underpinning data, the issue of adaptation was repeatedly described by the participants. Moreover in the free text area of the developed questionnaire the phrase '*it is ok now*' was frequently written, indicating adaptation to the appliance conditions (section 4.4.15 and 5.5.4).

The mean and median scores for Q1 were 33.97 and 29.5 and (SD 24.34) while Q4 were 80.5 and 85 (SD 17.26) (Table 4.27). This can show the difference between the patients' expectations about eating problems and their real problems after adaptation to the treatment. As such, we can conclude that patient expectations of eating difficulties was significantly higher than their real observations after adaptation to the appliance. The sensitivity in the detection of the difference between these two times also can be regarded as a persuasive reason for retaining Q1 in the questionnaire. Additionally, Q2 of this domain which asks about eating difficulties at the start of the treatment, produced a score was close to the patient expectation score (Q1) (Table 4.27). These results were consistent with the qualitative findings of the underpinning study (Carter *et al.*, 2015) which was used for the generation of the items in the questionnaire.

Lastly swallowing difficulty (Q6) was another item highlighted during test re-test reliability to be deleted in the questionnaire because there was a significant difference between the two times (

Table 4.19). Swallowing difficulty is one of the functional difficulties that patients will face, particularly at the start of the treatment. In order for the questionnaire to be a more patient based instrument it should include all the issues that reflect the patients' perception and experiences. In both UK and Kurdistan qualitative study swallowing difficulties were described by the patients particularly those with palatal expander or transpalatal anchorage and can be seen in different places in Kurdistan qualitative findings (This will also be discussed in the subsequent chapter). Furthermore, other studies also indicated both short and long term swallowing difficulties after insertion of the orthodontic appliances (Sergl *et al.*, 2000). Therefore this question was also retained in the questionnaire to cover this important issue which can show part of the functional difficulties.

During the content and face validity stages of questionnaire development, qualitative methods were used as a means for modification or reduction of the questions based on the experience of the

experts (orthodontists) and the experience of orthodontic patients, who can give more realistic clues for the modification. However, there are a wide range of complex quantitative methods used for questionnaire modification or item reduction across the literature such as factor analysis and rasch analysis. These types of tests aim to standardise the questionnaire text based on mathematical equations, but this does not necessarily lead to standardisation of the meaning of the words in the questions (Mallinson, 2002). However, using such complex mathematical methods for standardising questions or item reduction may jeopardise the patient-centred philosophy of the HRQoL instrument development. Mallinson (2002) indicated that qualitative validation of one of the most widely used health questionnaires, Short-Form 36 Health Status Questionnaire (SF-36) showed that some important problems were not covered properly and indicated that qualitative validation of the health questionnaire is more appropriate than quantitative validation. Ideally convergent validity would be an important test to conduct prior to applying the questionnaire to a larger sample but that there is not an appropriate instrument against which to test the developed ERQoL questionnaire. However, future research could simultaneously apply the ERQoL alongside another measure of QoL in orthodontic patients to test the convergent validity of the ERQoL score against QoL score.

4.5.5 Discussion of the Items Generated: the Impact of the Time during the Course of the Treatment

The database that underpinned the development of this questionnaire and the relevant literature indicated that most of the difficulties faced during orthodontic treatment are time dependant and related to the different components of HRQoL. After placement of the appliance most of the eating difficulties appear and lead to functional and social limitations. Therefore, in the developed questionnaire, there are a few questions which ask directly about time and its relation with eating difficulties during orthodontic treatment. One of the questions asks about the eating condition of the patients at the start of the treatment, *when you first got your braces, how did you find eating?* Moreover another question asks about the situation after adaptation with appliance, which is again a time dependent question (section 4.5.4). Using these two questions the patients can provide an overview about the difficulties from the beginning to the time of adaptation, Additionally the first domain of the questionnaire was named '*from the start and afterwards*' thereby relating to time and containing all of those questions which are directly or indirectly time dependent. These two questions (Q2 and Q4) can indicate the difference between the patients' experience of eating difficulties after placement of the appliance and their eating difficulties after adaptation to the appliances which mostly occurs after the first month of the treatment. Therefore, these two questions are important and can reveal part of the time dependant difficulties of orthodontic

treatment. In comparing the results of these two questions the difference between the expectations and reality of eating difficulties after adaptation to the appliance can be easily detected.

The qualitative data on which the questionnaire was based, indicated that there were some problems with eating difficulties which continue throughout the treatment. One the most apparent difficulties which was reported by most of the participants was stickiness of the food or food particles becoming stuck to the appliance. The issue of the stickiness of the food is addressed in the CPQ instrument which asks about the stickiness of food to the roof of the mouth and between the teeth. However, the stickiness of the food on the roof of the mouth was not reported in the qualitative data that underpinned the item generation in the current questionnaire, unless the patients had palatal anchorage devices or expander devices such as a trans-palatal arch, Nance appliance or quadhelix expander. In the initial draft of the questionnaire no questions were asked about the food stickiness but according to the recommendation of the participants during the face validity stage, a question about this problem was added.

The other impact of time is the progression of treatment which demands activation of the appliance at different times. By increasing the forces applied to the dentition during the activation, this may bring back some of the eating difficulties. These difficulties may not be the same as after insertion of the appliance but the patients still face some eating related problems. In the initial draft of the questionnaire this question was not included because the researcher thought that the idea of this question was covered in the other questions. Whereas in the content validity stage with the orthodontists, they recommended to include a question about the effect of activation on the eating related difficulties. Therefore a question was formulated for this situation which stated, *After your usual visit for tightening the brace what would happen to your eating?*. This question was inserted in the first domain *from the start and afterwards* because of its close relation with the time and progression of the treatment. This question shows that the eating difficulties are not only limited to the start time of the treatment but a continuous process with different magnitude and severity, as indicated by a mean score of 36 in pilot data (Table 4.27) with 0 indicating that eating becomes difficult after activation and 100 stating that it remained easy.

Expectation of treatment difficulties was also reported by participants in the UK qualitative study. This was also a time dependant variable and so the questionnaire aimed to explore the patients' expectation of eating difficulties before the time of treatment. Expectations of eating difficulties were expressed by only a small number of the participants in the underpinning qualitative data and this may have been due to the lack of awareness or information about eating difficulties and other QoL problems among patients and parents prior to treatment.. However, (Zhang *et al.*, 2007) indicated that most of the orthodontic patients did anticipate QoL deterioration, particularly

functional limitation due to the pain and the food restriction as the most noticeable examples. Therefore, in the first domain of the developed questionnaire a question was included about the expectations of eating difficulties after the orthodontic appliances were inserted to give us information about patients' preparation or compliance before starting the treatment (appendix A).

One of the common phrases that was used by participants in both qualitative studies was related to coping with the appliance after few weeks. Therefore, the effect of time was represented by the adaptation of patients to their orthodontic appliances, which generally occurs in the first few months after insertion. Serogl *et al.* (2000) also highlighted the adaptation of the patients to the orthodontic appliance conditions in terms of functional and social acceptance. Therefore in the questionnaire a question was dedicated to asking about eating after this period of adaptation had occurred. This question was also inserted in the time dependent domain (the first domain) of the questionnaire and the words "used to" were used to indicate adaptation to preserve the words of the patients in constructing the questions '*After you got used to your brace, how do you find eating?*' with VAS anchors '*difficult*' and '*easy*' included. During the test re-test reliability phase, this question was found to have a significant difference between the two response times (

Table 4.19 and section 4.5.4).

4.5.6 Discussion of Items Relating to Social Impact during the Course of Treatment

In the current questionnaire, one of the domains is entirely composed of social related eating difficulties experienced during treatment and tries to cover aspects which emerged from patients real experiences. This domain was named '*surrounding people and venue of eating*', which consisted of 7 questions asking different socially related questions such as eating with family, friends, unknown people and their concerns when they eat with these people. Furthermore there are questions about the venue of eating and the children's preference to eat alone when they are wearing orthodontic appliances. In the three most common OHRQoL instruments CPQ, OIDP and OHIP questions relating to school are present such as not wanting to attend the school, school homework and difficulty in concentrating on school work. This issue of the school is emphasised most in the CPQ due to the fact that the instrument is constructed primarily for child aged patients. The other eating venues like restaurants and friends or relative's house cannot be found in those three questionnaires. In relation to the surrounding people and the location these instruments also included some questions for example, the OHIP asks a question about the enjoyment of or being irritable in other people's company or avoiding going out because of the oral condition. In the CPQ there are also a few questions related to social well-being and eating such as not wanting to

spend time with or talk to other children. However, it is not clear whether these questions can capture children's perceptions and experiences regarding the eating difficulties with orthodontic appliances in relation to the venue of eating.

The research literature and the underpinning qualitative data (Carter *et al.*, 2015) suggested that family, peers, friends, surrounding people and venue of eating may be important in affecting eating related socialization of orthodontic patients during the course of the treatment. Sometimes the preference of children to a particular food can be affected by the influence of peers, because they like to eat the same food as their friends (Farrow *et al.*, 2011). The resemblance between the diet of children and their peers is highly important, as they may influence each other's eating, but no rigorous studies can be found, particularly in the dental and orthodontic literature. For children, school is one of the places that they may face eating difficulties with their friends or due to the time constraints which may encourage them to finish their meal sooner than ideal to keep pace with their peers. Therefore questions about the effect of surrounding people, friends and family members were included in the questionnaire. The options for the VAS anchors were uncomfortable and comfortable. In another question in this domain participants were asked to give their feelings about eating in front of family members at home. These two questions will give an overview about the children's eating venue preference and how they may feel which can be used in the instructions given to children and parents at the start of the treatment, to ensure they are better informed. Better information may help eliminate some factors which cause a deterioration in eating, particularly at the start of treatment. The results of these questions showed that the children's eating is more affected during eating with their friends (Q15, Table 4.27) in comparison with the eating with the family members (Q14, Table 4.27). This argument also can be seen in the UK qualitative studies in which the some of the participants showed their preference to eat at home alone or with the family members, so that they can eat as freely as possible without paying attention to their surroundings during eating which reduce their eating enjoyment. Most of the social deterioration can be seen in the (Q20, Table 4.27) which is about the acceptance or rejection of an invitation or offered food, where a very low score can be seen and this may show the impact of the appliances on the social limitations.

4.5.7 Discussion of Items Relating to Food and Drink Limitation

In this questionnaire two purely qualitative questions are included to ask the patients about foods and drinks that they avoid because of the appliances, to find out the impact of food selection and limitation. This allows patients to indicate the name of foods and drinks that cause difficulties during treatment. Furthermore, a free text area is provided for all the questions to derive as much information as possible about any limitations (appendix A). These two questions are purely

qualitative, without a measuring scale and therefore they cannot be analysed alongside the other quantitative questions. In both these stages (face validity stage and reliability testing procedure) the participants provided valuable answers in for both food and drink limitation and the majority of these answers were consistent between the two different times in test re-test reliability (section 4.4.15 and Table 4.22). Damage to the appliance and to the teeth was the most common reason for avoiding the fizzy and sugary drinks due to the dentist's instruction, while the avoidance of foods due to the orthodontist's instruction was regarded as the least common reason (Table 4.22). At this stage it is quite difficult to interpret the causes of this difference, however, when the instrument is fully deployed the data generated will help to more fully understand the reasons for food limitations. It may be that the hazard of those drinks is well known because advice to limit them comes from many sources and the dentists generally advise all patients (not just orthodontic patients) to avoid these drinks.

In both CPQ and OHIP some questions are included which investigate limitation of foods and drinks. For example in CPQ there are questions on difficulty eating the food what you like to eat and difficult in drinking or eating hot and cold foods. The second question limits avoidance due to the temperature of the food and drink. Marshman *et al.* (2010) conducted a qualitative study on the patients with a definite need for orthodontic treatment and evaluated the questions in the short form of CPQ (CPQ ISF-16) and the patients related the difficulties to eating or drinking cold or hot foods and drinks to the sensitivity of the teeth. However, both of the current CPQ questions may miss other foods and drinks avoided during orthodontic treatment such as coloured drinks and foods which may cause discolouration. Therefore it may be reasonable to include a question on the coloured food and drinks like *difficult to drink or eat coloured foods*. In OHIP a question on the food limitation is also present, but it is limited to the history of avoiding foods but not drinks. There is a question about the sensitivity of the teeth to hot and cold drinks, but no questions to investigate drink limitation. In the current questionnaire both drinking and eating difficulties are investigated using a qualitative question in hope of getting more precise and in-depth details of foods and drinks and the possible reasons behind them causing difficulties. The findings of these two questions in the testing procedure showed that a wide range of information can be collected and valuable reasons were indicated which represent different perspectives behind avoidance and limitation. This provides a strong indication for including the free text area in the ERQoL questionnaire.

4.5.8 Discussion of Items Relating to Changing the Eating Habit and Enjoyment During Orthodontic Treatment

Due to the progressive nature of the treatment, it is likely that during orthodontic treatment a new situation will be introduced to the patient's mouth that will bring some changes in eating and

introduce some new eating habits. The underpinning qualitative data suggested that acceptance of these new habits is mostly time dependant and individual factors also play a key role.

In the current ERQoL questionnaire a question about eating speed was introduced into the third domain *change that happened* (appendix A). The participants were asked to rate their eating speed from slower eating to quicker eating in comparison with before inserting the appliances, although in the Carter *et al.* (2015) qualitative study transcripts no participants indicated quicker eating. This label was included because the children may compare *slower* with *quicker* easily and therefore the *quicker* label was added to the second anchor of the VAS which represents better ERQoL. However, it might also be logical to put a label like *the same speed* because this would act as a reference point to which the participants may compare with the eating speed before the insertion of the appliance (appendix H). This adjustment to the rating label could be considered in future versions of the questionnaire (appendix H). In the other commonly used questionnaires like CPQ, OIDP and OHIP no direct questions relating to changes in eating speed can be found. However the CPQ contains a question about *taking longer to eat than others* which is indirectly asking about the speed of eating. In the data from the face and content validity phases, this issue can be seen more obviously and the participants mostly indicated that they are the last person who finishes their meal which is indicative of changes in the speed of eating. CPQ, OIDP and OHIP questionnaires are not specific to eating difficulties and to preserve the length of the questionnaire, it is not applicable to include too many questions related to eating difficulties. In a questionnaire about eating difficulties (Kelly *et al.*, 2012) the denture wearer was asked about the time they needed to eat a meal, because patients with lower chewing efficacy have a tendency to extend their chewing time in compensation (Helkimo *et al.*, 1978).

In the same domain a question was dedicated to measuring the change in the amount of food eaten in comparison with the time before having the appliance because this provides a landmark which they can refer to easily. This question was located in the third domain *changes that happened* and the anchors of this question are *eat less food* and *eat more food*. According to the qualitative findings (Carter *et al.*, 2015), most of the participants indicated a reduction in the amount of food eaten and related it with other factors like pain, slowness in eating, brushing and cleaning demands of the appliance and physical obstacle of the appliances. These arguments can also be seen in the findings of the qualitative data in Kurdistan-Iraq (Section 5.5.8). However, no-one reported an increase in the amount of food eaten and most participants indicated the same amount of food was eaten as before the treatment. Therefore, in the final version of the questionnaire the second anchor labels of the question could be changed to *I eat the same amount* (appendix H). The score of these questions (the eating speed and the amount of eating food), showed that the participants tended to

indicate their answers around the middle of the VAS scale (Q 10 and Q13, Table 4.27) which roughly means no change in the speed of eating and the amount of food eaten. The question about the change in the amount of food is a question which has not been previously described in any of the previously mentioned OHRQoL or eating specific questionnaires in relation to orthodontic treatment. Collecting information about changes in the of the amount of foods eaten is one of the important elements for a dietary assessment questionnaire (Salvini *et al.*, 1989; Hu and Bentler, 1999).

Eating enjoyment is the last domain of the questionnaire. Although all other questions have an influence in some way on eating enjoyment, these final questions focus on issues identified as the main causes of eating deterioration during the qualitative data collection. The questions are related to the functional and psycho-emotional aspects of eating related difficulties. Feeling embarrassed, being worried and the ability to eat the food that patients want are some of the examples of these questions. The CPQ asks one question about eating enjoyment by asking about *difficult to eat foods you would like to eat* contained in the functional related difficulties domain. However, in the current questionnaire this question was found to be more related to psycho-emotional aspects than functional because it tries to show the feeling of the patients when they are unable to follow their desire to eat the foods that they want to. Questions similar to the other two questions also can be seen in the CPQ questionnaire, but these are not directly related to eating, but are more general questions which ask about embarrassment and worries or frustration due to the dentition.

4.5.9 Discussion of item relating to the stickiness of food

In the current questionnaire a question about the stickiness of food was added to the second domain of *eating with your brace*. It is true that the problem of food stickiness is interlinked with other daily QoL activities such as social and emotional related problems but it was found that the physical and functional related problems are highly related to psycho-social eating related activities. The result of this question in the pilot testing (reliability stage) indicated a low score which reveals the problems patients face with food stickiness during treatment (Q8, Table 4.27). Food getting stuck was described on other occasions during all the UK qualitative investigations and this difficulty was found to have a connection with the other ERQoL factors. The initial question pool contained this question (food getting stuck with the appliance) while during reduction of the items at the research team level this item was removed because it was assumed that the qualitative question on the specific food avoidance may cover this question. However, during the face validity stage in the qualitative interviews some of the participants suggested adding a question on the stickiness of food and so therefore an item was generated.

A question about the difficulties of food particles sticking to the dentition and appliances also appears in the OHIP questionnaire (one question) although in the short form OHIP-14 this question was removed. Several studies have validated and used the OHIP-14 for determining OHRQoL of the orthodontic patients despite this important question not being included (Oliveira *et al.*, 2007; Feu *et al.*, 2013; Zhou *et al.*, 2014). Both the current study and Carter *et al.* (2015) indicated that food sticking to the appliance was regarded as one of the major problems during the course of the treatment (section 4.4.15 and 5.5.7.2). Therefore, this question should be present in any questionnaire that tries to establish the OHRQoL of the orthodontic patients. Food stickiness has close relationships with other problems and the phrase *food getting stuck* was found in many free text areas of different questions in different domains. For example, food stickiness interferes with eating, which affects eating enjoyment, sometimes participants want to avoid eating in front of others and prefer to eat alone so as not to be judged by others or embarrassed.

In addition to the direct question about the food stickiness, the qualitative question (Q9) (appendix A) asking about the food limitation will uncover those foods that patients avoid during treatment because of this and other difficulties. In the free text area some respondents indicated the reason behind avoiding certain foods and therefore inclusion of the free text area might enable increased understanding about food stickiness and its related problems. Surprisingly the problem of stickiness was the most common reason that limited participants' food selection as indicated in the free text area of the questionnaire (Table 4.22).

4.5.10 Summary

The ERQoL questionnaire has been developed, underpinned by data from a qualitative study by Carter *et al.* (2015) of child orthodontic patients. After qualitative analysis, an analytical index was formulated and used as a guide for indicating the questions of the questionnaire. The research team undertook the first line of item reduction. The content validity of the questionnaire was verified by 12 orthodontists who also participated in the questions reduction and modification. Patient-centeredness was emphasised in this study and they evaluated clarity, relevancy and comprehension of the questions by answering the questionnaire first and conducting a qualitative interview. They also decided the rating scale of the questionnaire (VAS) and confirmed the appearances and look of the questionnaire. Finally the questionnaire consisted of 28 questions, 26 questions with rating scale (VAS) and two questions without rating scale. For all the questions a free text area was provided for indicating the possible reasons behind the given answers.

In the reliability stage some statistical tests were performed to determine the internal consistency and stability of the questionnaire by using alpha correlation and test re-test reliability. During these procedures some questions were marked for deletion while the two qualitative studies confirmed

the importance and relevancy of those questions and therefore they were retained in the questionnaire.

The resultant ERQoL questionnaire is mainly focused on different aspects of eating difficulties during orthodontic treatment and the questions are more eating related and cannot be found in the other well-known generic questionnaire like CPQ, OHIP and OIDP. As such to some extent a valid and reliable questionnaire has been developed that will enable the determination of orthodontic patients' perceptions and the impact of orthodontic appliances in relation to various QoL aspects of eating difficulties.

A final version of the questionnaire is present in appendix H. However the questionnaire may benefit from further changes or clarification before it is used in a larger sample. For example Q3 is asking the children about the difficulties after the routine adjustments and the anchors are "become difficult and remain easy". These options are to inform the patients that whether the adjustment initiated the eating difficulties again or the difficulties are minimum or remained as low as before the adjustment. However, these two anchors still may be confusing and "becomes more difficult" and "remains the same" are other options that can be checked before applying the questionnaire in a larger sample. Q4 has mixed tenses and may confuse the children, therefore it is clearer to change the question in order to contain only one tense "After you got your brace, how did you find eating?". Moreover, it is more sensible to change Q8 to "When eating with your brace, how much of a problem is it to eat sticky foods?" in which the anchors of difficult/easy are more representative.

5 Chapter Five: Qualitative Study on ERQoL (Kurdistan-Iraq)

5.1 Introduction

5.1.1 Background information on Kurdistan

The next part of the PhD study was a pure qualitative study conducted in Kurdistan-Iraq, Sulaimani city. Kurdistan is a land belonging to the Kurds and historically they lived in a region surrounded by Zagros Mountains. Kurdistan is an ancient land with its unique ethnographic, linguistic and cultural characteristic. The Kurds are a nation without country and their territories now divided between four different countries, namely northern Iraq, eastern Turkey, north western Iran, southwestern Syria and a breakaway part of Armenia (Figure 5.1) (Husni *et al.*, 2006).



Figure 5.1 Kurdistan Map

The current study was conducted in Kurdistan of Iraq which is located northern of Iraq (Figure 5.2). Kurdistan of Iraq is the only part of Kurdistan that has its semi-autonomous ruling system inside the Iraqi federal government, which is known as Kurdistan Regional Government (KRG). KRG consist of four major cities namely Erbil the capital, Sulaimani, Dohok and Halabja.



Figure 5.2 Kurdistan- Iraq Map

The first medical education establishment in Kurdistan opened in Sulaimani in 1978 and the first dental school was established in Erbil 1995 in Siahaddin University and after one year the second dental school opened in Sulaimani University in 1996. Before 2000 all the dentists in Kurdistan were graduated from the other Iraqi universities such as Baghdad and Mosul Universities. The health system in Kurdistan is regulated by the Ministry of Health in limited cooperation with the Ministry of Health of Iraq in Baghdad. Due to the successive wars and sanctions since 1980 the infrastructure of the health system has been seriously affected (Tawfik-Shukor and Khoshnaw, 2010).

In Kurdistan dental health practices operate in both public and private sectors without a clear cut boundary between them. The main public services mainly start at morning 9.00 am to 12.00 am with a limited treatment option which are mainly primary care and mostly free of charge. The second option for the public dental health start at a selected primary care centre and dental hospitals, which starts from 2.00 pm until 6 pm. In these centres and hospitals most of the dental treatments are carried out and the cost of the treatments is predefined by the health directorate of the provinces. The third option is the private clinics which are preferred by most of the dentists and regulated by the Kurdistan Dental Association. Almost all the treatment options of dental practice are delivered in these private clinics. The cost of the treatment in the private services is not fixed and changes according to the dentists and places. In addition, unfortunately the quality of dental care and treatments in both sectors are not systematically regulated and not controlled by the relevant authorities.

Orthodontic treatment does not have a very long history in Kurdistan due to a lack of availability of this specialty. There is not any evidence in the literature about the start of the orthodontic treatment in Kurdistan or even in Iraq. However treatment has been undertaken earlier in other part of Iraq such as Baghdad, Mosel and Basra. The most important reason for this was having the facilities and orthodontic education at dental schools in these cities much earlier than in Kurdistan.

This not only applies to dental orthodontic treatment, but also to other medical specialties (Tawfik-Shukor and Khoshnaw, 2010).

According to the data of the Kurdistan Dental Association-Sulaimni Branch, around 30 orthodontists are available and do their practice in both public hospitals and private clinics. Due to the low cost of treatment, most patients try to seek treatment in the public hospital rather than private clinics. Similar to other places, in Kurdistan children tend to be the majority of the patients seeking orthodontic treatment, while adult patients are also can be seen in a large number of practices. This is mostly due the fact that orthodontic treatment only became available quite recently and most of the adult patients missed the treatment. Furthermore the improvement in the financial situation can be regarded as another cause which was mostly happened after 2003 when the international economical sanction on Iraq was removed.

5.1.2 Qualitative Research in Dentistry

Qualitative research entered the field of dentistry about four decades ago to provide greater in-depth and flexible approach to understand the patient's attitude and perception more comprehensively (Meadows *et al.*, 2003).

Historically in dentistry, research was mostly dominated by quantitative research. Dental trials in 2009 represented one third (34.4%) of all dental publications in comparison with 1973 which was only 5.8% (Richards, 2011). About a decade ago Meadows *et al.* (2003) reported that only thirty-seven papers utilised qualitative methods and the earliest one was published in 1976 in Germany which was about the use of fluoride. In dentistry qualitative research tries to answer some of those problems that cannot be approached quantitatively. Some questions have more psycho-social and emotional phenomenon and qualitative research tries to produce a relevant hypothesis in advance before any quantitative actions (Bower and Scambler, 2007).

At first, qualitative research in dentistry tried to identify beliefs and perceptions about oral health in general (Kiyak, 1981). In general, the majority of beliefs in oral health are limited to dental caries and gingival diseases (Kwan and Holmes, 1999) this may be due to the fact that these two conditions are the most common oral diseases (Petersen *et al.*, 2005). Selecting a qualitative method for detecting such beliefs and perceptions is the right decision (Mays and Pope, 1995; Östberg *et al.*, 2002) first, because of the nature of these studies which focus on beliefs and attitudes toward a particular dental health phenomena. Second, due the demand for in-depth knowledge and comprehensive perceptions which cannot be collected via numerical quantitative research. Therefore, having a comprehensive understanding about such beliefs encourages the oral health policy makers to address the adequate interventions. Kwan and Holmes (1999) conducted a qualitative study using focus groups based on age and gender. The results showed that concepts

around oral diseases are mostly linked with dental decay whereas periodontal disease among the younger age groups was not recognised as a dental disease. Despite the presence of gingival bleeding among older groups, this condition was still considered to be normal.

Another topic investigated qualitatively in the discipline of dentistry is related to oral health behaviours. Such types of study have been conducted on different age groups, i.e. older and younger age groups (Östberg *et al.*, 2002; Östberg, 2005; Borreani *et al.*, 2010). Moreover, this research has also been conducted with parents rather than the patients themselves, to find out the oral health behaviours of parents after certain dental treatment of their children (Amin and Harrison, 2009). These qualitative studies reveal the significance of the personal discussions on the improvement of the dental services and does not only see the patients as an object in dental therapy (Östberg, 2005). Selecting a qualitative approach is a correct way to investigate such phenomenon because it is already partly understood and quantitative questions are likely to only show part of the problem (Malterud, 2001; Östberg, 2005)

Exploring patient's experiences and perspectives about dental treatments and conditions is another theme for qualitative studies in dental research (Ingalill *et al.*, 2007; Griffiths *et al.*, 2008; Hyland *et al.*, 2009; Rousseau *et al.*, 2014; Wang *et al.*, 2015). In most studies patients were interviewed to give their experiences about different types of dental treatment. Semi-structured interviews and focus groups were the most common methods used in these studies. Such types of qualitative studies can be seen widely in the orthodontic field (Travess *et al.*, 2004; Mandall *et al.*, 2006; McNair *et al.*, 2006; Abed Al Jawad *et al.*, 2012). Some of these studies explored the impact of the orthodontic treatment on QoL and construct an instrument to be used with a larger sample.

Lastly, qualitative understanding is not only limited to studies of patients. The opinion of the professionals and practitioners is regarded as another form of qualitative study in the dental field. Practitioners mostly evaluate the treatment outcomes, provision of the dental services and identifying possible obstacles in the field (Cunningham *et al.*, 2000; Gussy *et al.*, 2006; Threlfall *et al.*, 2007; Nicol *et al.*, 2014). Furthermore, professionals and practitioners have also been involved in qualitative studies in order to assess the content and relevancy of items in patient-based instruments (Kelly *et al.*, 2012).

5.1.3 Qualitative Research in Orthodontics

In the orthodontic literature, qualitative studies have been performed on both surgical orthognathic and orthodontic patients. In some studies, qualitative approaches have been used to gather information from patients to construct an outcome measure (Ingalill *et al.*, 2007).

As with other dental research, focus groups and semi-structured interviews are the most common qualitative approaches that have been applied in orthodontic research (Masood *et al.*, 2010). Some of the studies used one or two ways of qualitative data collection approaches i.e. focus group and semi- structured interviews with orthodontic patients (Travess *et al.*, 2004; Mandall *et al.*, 2006; McNair *et al.*, 2006; Abed Al Jawad *et al.*, 2012). Using more than one method in data collection can be regarded as a source of triangulation and would increase the validity of the findings (Jick, 1979; Farmer *et al.*, 2006). Furthermore, qualitative studies in the field of orthodontics are not limited to the pure qualitative approach. In most of the cases the qualitative methods have been used to elicit background knowledge to develop a questionnaire by focusing on the patients perspective and experiences (Travess *et al.*, 2004; McNair *et al.*, 2006; Shelton *et al.*, 2015). These procedures were either performed in one continuous study, which included both stages or two different studies were used to address the problem and develop the outcome measure (Ryan *et al.*, 2009a; Ryan *et al.*, 2009b). Lastly, there are other types of orthodontic studies mainly dependant on previously validated measures and indices with a limited qualitative element (Bernabé *et al.*, 2008a).

Development of a topic guide is one of the essential steps in the process of data collection and this is usually prepared ahead of qualitative data collection so as to moderate a soft flowing discussion (Whitley and Crawford, 2005). In some orthodontic research not enough attention has been paid to this and topic guides were not clearly described in the published articles (Travess *et al.*, 2004). Whereas in some studies the topic guide was described, but the topic guide styles were not detailed by the authors (McNair *et al.*, 2006; Abed Al Jawad *et al.*, 2012). This may be due to journal word limits and to keep the report as simple as possible. However the topic guide is a sensitive and flexible aid that guides the researcher to follow the topic and as such reporting it is an important area (Whitley and Crawford, 2005).

More importantly, sampling strategies in qualitative studies are mandatory and it is necessary to coincide this with the research topic and the way of analysis (Marshall, 1996; Stewart *et al.*, 2008). In qualitative orthodontic studies, the most common sampling technique used is purposive and theoretical sampling (Abed Al Jawad *et al.*, 2012) whereas random sampling is not popular in orthodontic research (Whitley and Crawford, 2005; Masood *et al.*, 2010). However, random sampling has been used in some studies (Östberg *et al.*, 2002; Masood *et al.*, 2010). In contrast, random sampling strategies are mostly related to quantitative data collection in which the sample size will be determined in advance. Lastly, some qualitative orthodontic studies have not mentioned the sampling strategies nor the analysis method employed. These studies were mostly mixed methods and prioritised to develop a quantitative questionnaire based on the qualitative data

collection (Ingalill *et al.*, 2007). Therefore the detail of qualitative sampling strategies was under emphasised.

The sample size in qualitative study depends on data saturation technique (Masood *et al.*, 2010), which is a point at which no further analytical insight can be detected in the successive data (Ritchie *et al.*, 2003). Therefore the number of the samples are fluctuant and not stable. In a study on the dietary intake and behaviour during the fixed orthodontic treatment, the participant number was limited to 10 fixed orthodontic patient and therefore 10 interviews were conducted (Abed Al Jawad *et al.*, 2012). Similarly, Ryan *et al.* (2009b) interviewed 10 orthognathic patients originally, then conducted an additional 4 interviews with 4 more interviewees to increase certainty about the sample size. Although the data saturation, research topic and sample diversity decide the participant number, a sample size of only 10 may not cover all relevant issues around the topic of the study. For that reason 15 participants is often regarded as a minimum number when aiming to achieve data saturation (Guest *et al.*, 2006). Moreover, for most of the ethnographic studies 30-60 interviews are necessary before ceasing further recruitment of the sample to the study (Bernard, 2002)

McNair *et al.* (2006) used the two most common qualitative methods of data collection, focus groups and semi-structured telephone interviews with orthodontic patients who recently finished their active treatment. Focus groups can be arranged according to age, gender, type of treatment and other criteria of the study. However, the arrangement of the focus groups was not clearly described in the report of McNair *et al.* (2006). The arrangement of the focus group according to age is quite important to reduce the cognitive gaps between the participants. If different age ranges are included in the same focus group discussion, it is more probable that the flow of the conversation will be adversely affected (Heary and Hennessy, 2002). In addition, arrangement based on gender is another strategy to follow which may increase participant contribution, particularly when the participants are teenagers or the subject is more sensitive.

Participants in orthodontic qualitative research have not only been limited to the study of orthodontic patients, as clinicians have also participated in research (Cunningham *et al.*, 2000; Ryan *et al.*, 2009b); for example in studies developing outcome measures for orthodontic or orthognathic patients. The clinicians involved were interviewed qualitatively about their insight into the content of the developed outcomes or to aid with validating the content of the questionnaire. However, children and adolescents make up the majority of the patients who seek orthodontic treatment and most of the QoL studies in orthodontics are conducted with these age groups (McNair *et al.*, 2006; Ingalill *et al.*, 2007; Abed Al Jawad *et al.*, 2012).

The analysis of qualitative data varies among the different orthodontic and orthognathic studies (Bernabé *et al.*, 2008a). Selecting the analysis method mainly depends on the research question and the sampling. Framework analysis was used by Abed Al Jawad *et al.* (2012) and the sampling method was also matched by using purposive sampling. While in other studies the exact way of analysing the qualitative data was not mentioned which is a drawback (McNair *et al.*, 2006; Ingalill *et al.*, 2007). Grounded theory has also been applied to orthodontic qualitative research. In addition to those representing the findings of the qualitative data some researchers have included verbatim quotes (Burnard, 2004; Clissett, 2008) whereas others have not (Ingalill *et al.*, 2007). It may be argued that including quotes may disrupt the reader and does not allow them to follow the findings according to the raw data. On the other hand the inclusion of verbatim quotes clearly positioned in the report allows the readers insight into the analytical processes (McNair *et al.*, 2006).

Much of the qualitative research in the orthodontic field has been linked to questionnaire development (Ingalill *et al.*, 2007; Ryan *et al.*, 2009a; Ryan *et al.*, 2009b). These studies dealt with the problems that face orthodontic patients during and after the treatment. They mainly focused on the pain and functional difficulties such as biting and chewing difficulties due to the pain initiated by the orthodontic appliances. On the other hand, other studies tried to use the qualitative studies to develop a questionnaire on patient satisfaction with the orthodontic treatment for the health care providers (McNair *et al.*, 2006). ERQoL was not the primary focus of most of the previously published studies and only little research has been performed in this area (Abed Al Jawad *et al.*, 2012; Johal *et al.*, 2013). Therefore, it can be concluded that the literature of orthodontic research has not investigated eating related QoL to any great extent.

5.2 Aims and Objectives

The Aim of this study was to explore in depth ERQoL from the orthodontic patient's perception in a sample of Kurdish adult and child patients.

Objectives

- To use semi-structured interviews and focus group to obtain data on the impact of orthodontic treatment on ERQoL in Kurdish adult and child populations.
- To compare the qualitative data in the UK population with data collected from the Kurdish population to determine common culture and age specific themes.

5.3 Introduction to the Methods in this Study

5.3.1 Interviews

The interview has similarities with the ordinary social conversation, but the conversation will be conducted with a particular purpose which is defined by the research question. These conversations mostly use open questions and try to create stress free circumstances to allow the participant to communicate with the researcher naturally. These types of questions are mostly used to find the answer of the research question (Edmunds and Brown, 2012).

There are several types of qualitative interviews, such as structured, semi-structured and unstructured interviews. Structured interviews are quite similar to questionnaire surveys in which closed questions are predetermined and will be asked to the participants with no chance for further elaboration. By contrast, in unstructured interviews predetermined questions are not available and this allows the researcher to explore in depth information about a subject where there is currently little information present (Gill *et al.*, 2008).

On the other hand semi-structured interviews are in the middle between these two interview techniques and was the method of choice for the data collection in this study. Here most of the questions are open, verbal, and direct and the researcher should make as little contribution as possible in the conversation (Melia, 2000). Although the priori experience of the interviewer is still controversial, it is essential to utilise it correctly in order not to miss the interviewee's pure feelings, experiences and perceptions (Britten, 1995). On the other hand the background information and experiences are useful for the researcher to probe the emerging themes, developing and reformatting the topic guides.

5.3.2 Focus Group

A focus group is a form of communication between the research participants, working together to collect data for the researcher. Using this method, it is practical to collect data from several participants at one time. The aim of this approach is to enable the participants to exchange their experiences, points of views and ideas about a topic and the researcher tries to encourage them to talk to each other (Kitzinger, 1994). The focus group was used in this study as a way to give a breadth of information about the topic of the study, to give confirmation to the findings of the semi-structured interviews and as a triangulation method to increase the validity of the qualitative data (Jick, 1979; Farmer *et al.*, 2006).

There are some advantages of focus-group such as:

- Identifying the norms of the group
- Engaging with a variety of communication methods and wide-range of understanding

- Respondent's priorities, attitude, and language can be uncovered (Kitzinger, 1994).

In this study, both of the above qualitative methods will be employed to investigate ERQoL in a group of Kurdish adults

and children.

5.4 Subjects and Methods

In this study two methods of data collection were considered which were semi-structured interviews and focus groups. These two methods are the most common methods applied in health and dental research (Gill *et al.*, 2008; Masood *et al.*, 2010). For gathering information from the respondents in a scientific way the interviewer must be trained and know some basic information about qualitative data collection (Blinkhorn, 2000). Therefore the researcher participated in two intensive courses on qualitative study and analysis arranged by both Newcastle University Faculty of Humanities and Social Sciences and Surrey University (appendix I).

5.4.1 Ethical Considerations

Ethical approval for the qualitative study in Kurdistan-Iraq was granted by the Ethical Committee in Medical Faculties at Sulaimani University (appendix B2)

5.4.2 Sampling and Recruitment

Sampling in qualitative research needs to be appropriate and adequate. Appropriateness means selecting the right participant who can enrich the study with valuable data, while adequacy is related to the amount of the data required and recognition of when data has become saturated and no further recruitment is necessary (Morse and Field, 1995). In contrast to quantitative research, sampling in qualitative studies cannot be randomly determined and therefore cannot be generalised. However the aim of qualitative research is not to indicate the distribution of a variable, it mostly tries to explore perceptions (Koerber and McMichael, 2008). In health research sampling strategies are more precise and systematic terminologies have developed to reflect the rigour of qualitative research. Therefore, in the last few decades more suitable ways of qualitative sampling have been defined by health researchers (Coyne, 1997).

The three most common methods of sampling are convenience, purposeful, and theoretical (Koerber and McMichael, 2008). The sampling strategies for this qualitative study involved purposeful sampling techniques. This was to include different patients with regards to the time of the treatment so as to reduce the effect of being unable to remember a past event, particularly for those who were in the end stages of their active treatment. Purposeful sampling is applicable when the researcher includes particular participant with particular features based on the aim of the research (Coyne, 1997). In purposeful sampling the researcher looks for maximum variation within

the selected population of the study (Coyne, 1997; Meadows *et al.*, 2003). Moreover, the researcher's framework and interest will play a role in selectively including the participants, therefore they will not be changed throughout the study. For the qualitative interviews 58 orthodontic patients were approached. The patients were first approached by their orthodontists who informed them about the study verbally. The orthodontists briefly introduced the scope of the study to the orthodontic patients and parents. Those who were interested in participating in the study were given a participant information sheet delivered by the researcher at the same visit with the orthodontist. The information sheets contained more information about the study and what the participants would have to do (appendix D2). The researcher asked both the participants and the parents to read the information and contact the researcher by phone if they were happy to participate. After contacting the researcher an appointment was scheduled for the interviews and they were asked for a convenient time and location. This process facilitated selection of appropriate sample. On the day of the interview the researcher asked both orthodontic patients and the parents of the child participants to read and sign the assent or the consent forms (appendix C2).

For the focus group discussion the participants were recruited using the same strategy as the interviews and in the same locations. Four focus group were planned, structured according to age group and gender. In total 73 patients were approached to participate in the focus group discussions and divided into four discussion groups based on age and gender. It was planned to have a minimum of 6 participants in the adult groups and 5 in the children focus groups.

The interviews and the focus groups were conducted by the researcher in a quiet place in the dental hospital or the private clinics and all the interviews and focus group discussions were audio recorded. All participants were assured about the confidentiality of the interview and that their name would not appear on any of the documents. In order to make the interviewees more confident they were allowed to be accompanied by their parents for children and friends/parents of the adult patients particularly the female adults. In the focus group only the participants were allowed to enter the meeting room and the researcher encouraged them to keep the confidentiality of the other participants. The researcher also did not reveal himself as a clinician and did not wear his uniform so as to make the interview as natural as possible.

The research plan was to investigate the effect of different types of appliances including fixed, removable and functional appliances.

5.4.3 Topic Guide

Most importantly a topic guide should reflect the research question and can be developed from existing literature and personal and clinical experience in the area of the study (Campbell, 1999). In addition, different types of interviews require different strategies for developing the topic guide

questions. In this study the topic guide was developed primarily from previous qualitative work conducted by Carter *et al.* (2015) at Newcastle University, School of Dental Sciences. The second source was the researcher and research teams' background in orthodontics and ERQoL.

The topic guide for the interviews (appendix E1) was developed in ahead of the focus group topic guide. This was mostly because the interviews were conducted in advance and therefore findings from these were used to inform the focus group topic guide, which closely reflected the interview topic guide. The interview topic guide was developed by the researcher, revised by the supervisory team and corrected accordingly. After initial interviews some new questions were added to the topic guide. At the later stage of the interviews the topic guide was modified again by adding, removing and changing the sequence of some of the questions. In the focus groups topic guide (appendix E2) nearly the same strategies were used for the questions, but some other forms of activities were added to the topic guide such as role playing, card and paper quiz. At the beginning of the discussion the researcher asked the participants some questions about their brace and eating. The participants answered the question on a separate piece of paper and returned this to the researcher at the end of the discussion. The other activity was role playing where one of the participants played the role of the orthodontist and the other one was a patient. The researcher asked the first one, how you would instruct your patient about eating and how they should manage eating difficulties. The second role player was requested to ask any questions about their issues related to eating and the brace.

5.4.4 Process of Data Collection

Interviews and discussions continued until no new information emerged and data saturation was reached, the point where further sampling and interviews were unlikely to provide new information (Ritchie and Spencer, 2002). All focus groups and interviews were digitally recorded and transcribed to capture data to provide a reliable record (Seale and Silverman, 1997). Themes were developed by the researcher.

In the focus group discussions, in order to make a fluent conversation attempts were made to make the discussion group homogenous, therefore the participants' age and genders were considered. During the discussion the researcher tried to keep the conversation between the participants rather than just asking questions and answering. During the discussion sometimes some of the members were silent and the researcher attempted several times indirectly to engage them into the discussions by asking a question like "what about you... how did you deal with such a situation". More dominant members were controlled by the researcher using phrases like "thank you, that is really good information, but let me ask (another participant name) what he likes to tell us about this" or "ok, what about you, any further idea".

It was anticipated that the focus group discussion with children would be more complicated than the adult group and that extra effort would be needed to keep some control. Therefore fewer members were recruited into the child focus group compared with the adult group and attempts were made to recruit participants of a similar age.

5.4.5 Analysis

Framework analysis method was used for the analysis of the data (Ritchie *et al.*, 2003). After development of the analytical framework which is sometimes called the “index”, the process of analysis started by developing a chart and categorizing the themes according to the analytical frameworks. The charting technique was used to organise the data regularly according to indices and to allow easier referral to the participant quotations (appendix F). For the analysis of the qualitative data Microsoft Word software was used as the Kurdish alphabet was incompatible with the Nvivo software. With manual analysis and using a charting method for the data simplified the analysis and meant that it was achievable without using specialised software.

The analytical processes were started during the data collection phase, to inform the ongoing procedure of data collection (Pope *et al.*, 2006). After primary analysis of the data, the nature and characteristics of the sample changed and so this approach allowed for refinement of the questions in order to extract more in-depth information. The primary analysis indicated the necessity of recruiting orthodontic patients at different treatment times and thus the recruitment procedure was changed to consider this.

For the framework analysis 5 different steps were followed to analyse and summarise the qualitative data which were linked to each other (Fig 5.3).

- The first step was familiarization which was the initial stage by immersing deeply in the data to identify initial themes. This step was reinforced by transcription of the qualitative data by researcher. Furthermore, reading and listening to the data several times enhanced the familiarization. In general, familiarization with the data was a crucial step in qualitative analysis and continued until the researcher was convinced with understanding the diversity and characteristics of the data (Ritchie *et al.*, 2003). The themes were not always `apparent in the transcript and it was the researcher’s role to uncover them. This was performed by deep and repeated reading, writing memos and summarising the entire data (Pope *et al.*, 2006).
- The second step was development of a thematic or analytical framework or index based on the identified themes, which was then refined and modified according to themes which emerged from successive interviews. A set of categories or “analytical frameworks” were developed and used to organise the data. The framework analysis allows researchers to

compare and contrast the data easily, either across all the qualitative data or within individual data (Gale *et al.*, 2013).

- The third stage was indexing the analytical framework systematically on all data transcripts.
- Charting was the fourth stage which involved collection of the all data in a chart which is then categorised according to the previous thematic framework. Charting makes it easier to refer to the data, summarises each participant's data and compares it with the data of other participants.
- The final stage was mapping, where the dataset is analysed collectively and mapped together to determine the general interpretation and presentation of the data.

During the transcription several initial themes were recognised and these were recorded on separate sheets which were used during the subsequent analysis procedures.

In order to be more realistic and sustain the trustworthiness of the qualitative data, the framework analysis was performed on the raw Kurdish data and analysed in Kurdish language. This reduced the chance of losing ideas and concepts during the translation of the qualitative data as well as allowing the researchers to analyse the data according to the natural verbatim. At the start of the qualitative data collection several transcripts and the initial analysis were translated into English language by the researcher to allow the supervisory team to be aware of the process and to obtain their comments and feedback about the data and data collection procedure.

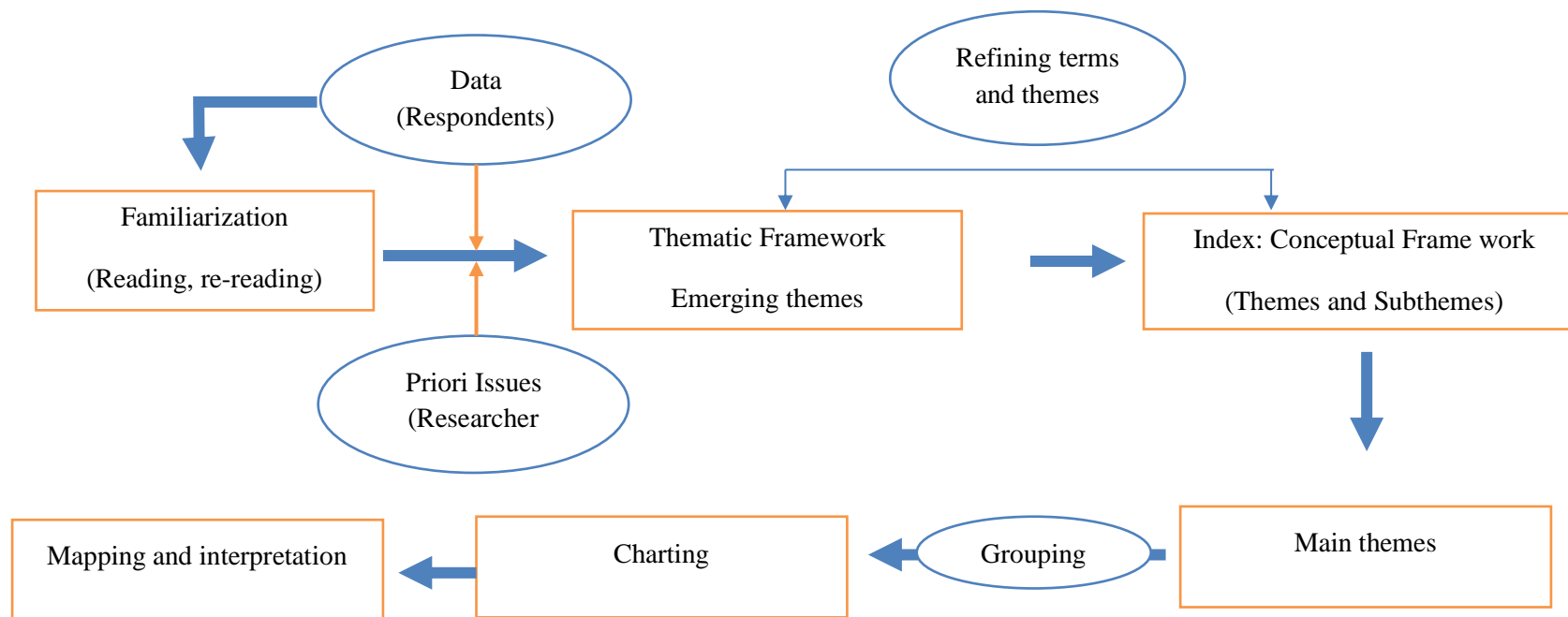


Figure 5.3 Framework analysis scheme. Adapted from (Pope *et al.*, 2006).

This figure shows a summary of framework analysis. After familiarization with both data and priori frameworks, emerging themes identified. By refining the terms and themes a conceptual framework (index) introduced which consisted of themes and subthemes. After identification of the main themes by grouping the original data according to the themes and subthemes of the index together in a chart, this allowed easy interpretation and reference to the themes.

5.5 Results and Findings of the Qualitative Study in Kurdistan-Iraq

For the qualitative interviews 29 semi-structured face to face interviews were conducted with two age groups, children from 11 to 16 years and adults from 17 to 25 years old, the majority with fixed orthodontic appliances. These participants were approached and recruited from the Sulaimani Dental Hospital and a few private clinics. Eight of them refused to participate the study on the same day of approaching. Whereas 21 approached patients indicated they were happy to conduct the interviews, but failed to participate either by not coming to the interview or by notifying the researcher earlier. In total, 29 patients participated and the interviews were conducted (Table 5.1 and

Table 5.2).

For the focus group 73 patients were approached and about half of them rejected to participate immediately after the verbal introduction. 20 more potential participants contacted the researcher and then made their final decision to not take part in the discussion. The remaining 22 patients were scheduled for the focus group discussions (Table 5.1). On the day of the discussion 2 adults and 1 child male members were absent, but all the focus groups were still conducted. The adult male focus group needed to be rescheduled twice after the presence of only two members. In the end, 4 focus groups were conducted; an adult female group (6 participants); an adult male focus group (4 participants), child female group (5 participants) and child male group (4 participants)

Table 5.1 Approached, rejected and accepted participants' number and percentage.

	Approached participant	Rejected on the same day	Rejected later	Accepted to Participated	Participated
Interviews	58	8 (12%)	21 (36%)	29 (50%)	29 (50%)
Focus groups	73	31(43%)	20 (27%)	22 (30%)	19 (26%)

Table 5.2 Characteristics of participants in the semi structured interviews.

	Number	Gender		Age		Time of the interview		Treatment time/month		
		Female	Male	Mean	SD	Mean	SD	Mean	SD	Range
Children	13	7	6	14.3	1.7	17.1	4	12.9	8.9	1-36
Adults	16	10	6	21.3	2.9	19.5	6.7			

For the presentation of the results, the themes and the subthemes are supported by quotes which express as far as possible different participant's viewpoints to show the diversity of the responses. However, sometimes it is impractical to cite all the quotes for a particular theme because this would be unnecessarily repetitive. Therefore the findings are provided here in summary with more detailed description of the points which need more probing and clarification.

Here the themes and the sub themes in both interviews and focus groups and for children and adults are presented together because most of the concepts are not isolated but interlinked with each other. However, all the themes and sub-themes are described to provide a clearer and more comprehensible evaluation. After the qualitative analysis 10 broad themes were found in the data and sub-themes identified within themes which needed further categorization.

1. Expectations regarding the orthodontic treatment

1.1 Predictions

1.1.1 Pain

1.1.2 Eating

1.1.3 The appearance

1.2 Expecting the treatment to be easy

1.3 Comparison of expectations and experience

2. Delaying the orthodontic treatment

3. Feelings about orthodontic treatment – hopes and regrets

4. Eating with the orthodontic appliances after its placement
 - 4.1 First few days
 - 4.2 After the first week
 - 4.3 After the second week and on ward subsequently
5. The impact of routine adjustment (activation) of the appliances on eating
6. The impact of brace de-bonding or appliance breakage on eating
7. Food selection and limitation
 - 7.1 Soft diet
 - 7.2 Sticking of different kinds of foods to the orthodontic appliances and its impact on eating
 - 7.3 Hard and chewy foods and their impact on the patient during orthodontic treatment
8. Changing the eating habits during orthodontic treatment
 - 8.1 Chopping the food into smaller pieces
 - 8.2 Using smaller mouthfuls
 - 8.3 Slower speed of eating
 - 8.4 Retaining the food for a longer time inside the mouth
 - 8.5 Eating less and weight change
 - 8.6 Using hand, lips and tongue at the time of eating
 - 8.7 Using hand to hide the appliance during eating
9. Social relation and eating with having orthodontic appliances
 - 9.1 Eating with others
 - 9.2 Eating alone
 - 9.3 Eating outside
 - 9.4 Rejecting invitation or offered foods
10. Enjoyment of eating
 - 10.1 Eagerness for eating
 - 10.2 Not eating their favourite foods
 - 10.3 Taste change

10.4 Eating cautiously

10.5 Inability to speak freely during eating

10.6 Giving up eating without feeling full.

*M 15 FF, ** Sh. 14 FF CFG*, examples of the coding system for the Kurdistan qualitative interviews and focus groups. M and Sh represent participant's letter, 15 and 14 represent the age of the participants and the F represents the gender, F represent type of orthodontic appliance (fixed appliance) and CFG for focus group (child focus group).

5.5.1 Expectations of orthodontic treatment

This section describes the patient expectations of orthodontic treatment before starting their treatment and determines the role of eating difficulties within these expectations. Moreover, in this section the outcomes of the expectations were explored to know whether the treatment was easier or more difficult than their initial expectations and whether eating problems affected this evaluation.

5.5.1.1 Expectations

Although not emphasised in the original topic guide, in their interviews, patients frequently talked about their expectations prior to commencing treatment. Most of the participants expressed that they expected to experience difficulties during orthodontic treatment and several recurring factors were predicted by patients. Although some of the themes explored were not primarily related to eating difficulties, they are recorded to give a wider picture about the prediction towards treatment and where the predicted eating difficulties would stand. In addition, prediction of difficulties during treatment can be categorised as a theme that was mainly age dependent and concerns were mostly expressed by the adult group.

a. Pain

One of the most common predictions for the treatment was pain and thinking about the painful procedures that the treatment might bring later on. For some patients such predictions came from previous experience with other dental work including orthodontic treatment, friends or relatives who underwent difficult orthodontic treatment or not having any reliable information about the treatment.

*I thought that it would be difficult because my previous appliance was too difficult, I was afraid to have lots of pain as the other one... M 15 FF**

At first, I thought that it needs surgery, anaesthesia, making a hole in the teeth, I did not have any information about it and I have never seen such thing before, I was really scared... R 21 FF

At the start I thought it is not so much difficult, I thought it would be easy but when my sister-in-law has put the brace she faced lots of difficulties and pains so I thought it is the case and it is not as easy as I think... K 25 FF

I have seen lots of people with brace and I thought how they can tolerate such horrible things and how they cope with it, it was really seem to be difficult....actually I was afraid of its pain and I knew that it is definitely needs dental extraction and also with the brace all my teeth will be tied together which is really annoying.... H 19 FF

b. Eating

Eating difficulties were also predicted by a number of the participants but it is obvious that the prediction of eating difficulties was less than pain prediction because pain was the most common word cited. Some of them related the difficulties to the physical nature of the appliances and its bulkiness which may prevent eating.

...but I thought that it would be difficult because all of those stuff must be in my mouth and how can I eat with all of those things and actually I was right and my eating was really difficult... D 25 FF

I have said to myself that the brace may mess up your eating because lots of stuffs have to go to my mouth and it actually happened and my eating was really very annoying at the start of the treatment...A 20 MF

I expected it to be very hard, I have seen others with brace who had eating and speaking difficulties, and therefore I thought it would be difficult for me as well... I was worried about the food particles collections and stickiness which would make my mouth dirty....also I thought I could not eat properly...Sh 14 FF

I thought I also would be like my brother, he always had a soups and soft diets, his eating was abnormal and was very little, he couldn't bite the foods regularly ... S 25 FF

I have thought that it might be an obstacle for speaking and eating. Also I thought that it would make my life difficult, really I did not know what will happen, everyone has told me that the difficulties are only in the first few days and then you will be familiar with it. Honestly, I did not believe them because I thought that these are just for

encouragement in order to start the treatment. But I imagined that the difficulties would remain until the end of the treatment...R 21 FF

c. The appearance

The other most common expectation was the issue relating to the appearance of the orthodontic appliances and this mostly related to the fixed orthodontic appliances. The other factor that made them worry more about the appearance was the lengthy treatment time.

It might be very obvious although I just wanted to have a straight teeth and nothing more, but I thought if I put a brace I may not be able to play with my friends in the patch because if they made any mistake my mouth will be full of blood...P 19 FF

- I thought it would be very difficult, it is very difficult to have all of these wires inside your mouth, it is very obvious and can be seen easily by others. It takes a long time to finish and also I thought about its cost and multiple visits and transports. I have thought a lot about those things beside of this it makes my lower jaws very heavy... Sh 25 FF

I don't know what to say, my teeth were very proclined and the front teeth also badly overlapped, I said if I put the brace it would be completely observable and now I can't laugh easily or take a picture, when I laugh I have to do like that (She put her hand in front of her mouth to hide the brace- from the interviewer notes) ... D 25 FF

5.5.1.2 Expecting the treatment to be easy

On the other hand not all the participants predicted difficulties, and some of them thought that the treatment would be easy. They reported that they mainly had such expectations because they just want to have nice and beautiful teeth.

You can't earn any things without pain and difficulties, I want to have nice and beautiful teeth, so I don't care about the difficulties. I have prepared myself for everything so it appeared to be easier...F 14 FF

It was better than I expected, I thought it will brings lots of difficulties and pain to and makes my life difficult and every one gaze at me. Although some difficulties happened but I have coped with it very quickly ... P 19 FF

*Even before the placement I imagined that it will not hurt me a lot, most of my friends told me it would make you thin and you would be unable to eat anything. But I really thought it is easy and believed that it is not going to bring any difficulties to me... Sh. 14 FF CFG***

5.5.1.3 Outcome of the expectation

After starting the treatment most of the participants realised that the treatment is not easy and for some of them it was harder than they had expected. Interestingly, most of them realised that eating was one of the biggest challenges after the insertion of the appliances. Furthermore, some others related the difficulties to pain, as they were expecting pain before the treatment. After the placement of the appliance they found that eating related pain is another source of pain.

My friend has had a brace before and I already knew that she cannot bite with her front teeth, she has to chop it into very small pieces and then eat it and I knew that she got pain when she eats. Therefore to some extent I knew that it is going to be difficult and really it is.... K 24 FF

It was more difficult than I expected, I never expected to have such a lot of pain during eating. At start of the treatment I couldn't bite any things. Even when my teeth contacted each other I felt lots of pain. I couldn't eat well and the brace by itself was heavy and I couldn't chew properly therefore many times I stopped before finishing the meal... 17 FF 25

Eating completely became difficult and it was very strange, I couldn't eat with my front teeth and couldn't catch or bite anything therefore my eating amount reduced remarkably... A 20 MF

Before the placement of the brace I always thought how to eat, but now it is very upsetting and affected me too much. Now I feel stomach pain regularly due to the sudden reduction of my eating foods... K 25 FF

However other patients found that the brace was less problematic than they had anticipated.

No I think it was good, I think the difficulties were lesser than that I expected... B 16 FF

5.5.2 Delaying the orthodontic treatment

Some of the participants discussed the issue of delaying their treatment, particularly the adult group and that they had previously thought about treatment but decided to delay it to another time. Eating problems were identified as one of the primary causes for this decision which was mostly linked with anticipated pain and discomfort. They mostly learned about those difficulties from the experiences of others who were under treatment or finished treatment.

Actually I was afraid a lot so I have always rejected insertion of the appliance. I have seen some people who had a brace and they told me it is not easy and you can't eat anything. They said it will injure all of your mouth so you can't eat regularly.... My

parents tried very hard to persuade me to insert it but as I have seen those with pain and eating problems I was not ready. But when I had inserted it I realised the difficulties were temporary just at the start of the treatment... Rs 21 FF 16

I thought it would definitely diminish my eating or it would make my eating very problematic and this was the main reason I have not started the treatment earlier. I was just a kid at that time and I didn't know what this really is, but when I grew up I realised the necessity of the treatment because my teeth were very irregular and they needed to be corrected... S 18 MF

There were other causes given for the postponing treatment and they were mostly related to fear of pain, cost and appearance of the appliances.

My sister has a brace and she kept telling me that after the tightening it became very difficult again, even she couldn't study well because of the pain and other difficulties so this made me doubtful and has delayed my decision to insert the brace. B 16 RF CFG

I live abroad and the cost of treatment there is very high, so I have waited to start the treatment in Kurdistan, I think it is the same thing but here can be done with much less price. K 25 FF

The brace is very obvious and it is not nice all of those wires and metals to be seen inside your mouth and it has to remain there for a very long time especially for me in which my age increasednow with my brace I always try to hide it with my hand during laughing, speaking or even during eating.... La 22 FF AFG

5.5.3 Feelings about orthodontic treatment – hopes and regrets.

Most of the participants were happy with their brace and this was mostly linked with the imagined outcome of the treatment such as a beautiful appearance and smiling. On the other hand some of the participants have related their regrets to problems that they have faced during treatment. Eating was one of those factors that pushed the patients to have such thoughts, particularly at the start of the treatment. Surprisingly, one of the participants was ready to discontinue the treatment as a result of continuous loss of her body weight.

Sure, if you want to have a cosmetic procedure for any part of your body some difficulties will come and you have to face it strongly. It is just at the start of the treatment when you can't speak and eat properly, your mouth gets hurt with lots of injuries but the advantage is for yourself and the teeth would become beautiful. K25 FF AFG

I never thought that the brace is so much difficult, I don't know this may be because I have recently had it placed; it is very painful and I cannot eat the normal food. But if the difficulties go on in such a way I may regret the treatment.... I know this may be impossible because my parents and my orthodontist will not agree with this. H20 FF AFG

For several times, I have cried and have told my parents that I want to remove it because it really makes my life difficult, especially the first month. R 21 FF

I have lost my weight a lot and this really upsets me and I think it is because of the brace because I cannot eat well and I eat very little amount of food... losing body weight for somebody is good but not for me, I was already thin. I have asked my orthodontist several times to remove it but he persuaded me to retain it. Really I don't know what to do, it takes ages to finish the treatment... H 19 FF

5.5.4 Eating with the orthodontic appliances after its placement.

It is obvious that eating with an orthodontic appliance is subject to change according to time. Closer to the placement date eating is likely to be more difficult. For a better understanding of situations patients face whilst eating after insertion of their appliance, it is useful to classify it into different periods of times according to the experience of the patients in terms of functional difficulties during eating.

5.5.4.1 First few days

This includes the first day after insertion of the appliances. This also includes the first day after insertion of the elastic separators which may be regarded as the first step of insertion of the appliances. According to the reports of some of the patients, on the first day after both occasions the eating difficulties were increased but not generally in relation to the pain. Although the pain had initiated and was affecting them, the intensity of the pain was still tolerable and actions like biting and chewing can be performed. Whereas the physical characteristics of the appliance itself was regarded as the main obstacle for eating difficulties, rather than pain.

It was a strange thing, at first it was ok but after few days the pain started, eating became very difficult. I couldn't bite with my front teeth or grasp anything... K 24 FF

The first night was ok but then the pain started. All my teeth were heavy and the elastics between my teeth really hurt me. After the placement of the brace, the first day was very uncomfortable. I wanted to eat really, I didn't know what to do with the morsel inside my mouth, and just I passed it side to side and stuck to my brace. I wanted to swallow it but I couldn't.... B 16 FF

I didn't know these things would happen. It was painful and I couldn't eat anything, just the soft foods. For two days those difficulties remained, I couldn't bite with my teeth... B 11 FF

On the other hand for some others the pain and eating difficulties started on the same day of the insertion of the appliances or the elastic separators. Pain and physical obstacles of the appliance and elastics were regarded as the main causes for those difficulties. Furthermore, a sudden change in the oral conditions and unfamiliarity of the oral soft tissues and musculature with the appliance was another factor which increased the level of difficulties. During the next few days, most of the participants reported eating difficulties due to the pain, brace itself and soft tissue injuries. This problem was mostly related to patients with fixed orthodontic appliances, while for removable appliances eating difficulties were reported to be minimal because the appliance can be removed during eating. Issues around removable appliances could not be expanded to discover more details because only two participants had such appliances.

I had pain in all of my teeth, there was spontaneous pain. After few days I had pain in all of my mouth, my tongue, my lips and cheek inside were injured by the brace, I have to put on ointments just to lubricate it. Hot or sour food increased the pain... K 14 FF

Eating was uncomfortable, I couldn't eat like before I had pain so I couldn't use my front teeth but the back teeth were better. I thought that the brace tries to pull all the teeth and it is like that you cannot press the food inside your mouth... K 24 FF

Exactly from the first work I had pain. My orthodontist put some elastics between my back teeth. It was really annoying. One side was better and I relied on that side every time for eating. My eating was changed and I thought my teeth do not contact each other... A22MF AFG

In addition to having pain in my teeth the brace also rubbed my lips and cheeks inside and doubled my difficulties. I think it is a good idea to change the shape of these brackets because it really injures the lips and cheeks inside... N 24 FF

5.5.4.2 After the first week

For most of the orthodontic patients towards the end of the first week is the time when the pain gradually subsides and they become more familiar with the appliances. One of the common themes that all of the patients in both interviews and focus groups agreed was shifting to a soft diet and avoiding some of the routine foods and this of course included hard and chewy foods. This can be regarded as the time when the participant tries to start changing some of their normal eating habits.

I couldn't eat anything, when the morsel was inside my mouth I did know what to do with it and sometimes I brought it out. For more than a week I was like that but then gradually I have coped with it because you have to eat something. In that time I had soft diet because I couldn't eat as normal, I had mostly biscuit with tea, now it is much better...D 25 FF

When I eat anything I go to clean it immediately so as not allow anything to remain on my brace. Actually this is not comfortable and sometime you would get bored. I was afraid of having such a lot of brushings may bring something bad to me...K 24 FF

I have just soft foods for two or three days and then I adapted to the situation of the brace... I couldn't bite all of my teeth were tight and I had pain in all of my teeth...Rs 21 FF

5.5.4.3 After the second week and subsequently

This time can be regarded as the time of maximum adaptation and coping with the new situation of the appliance. However most of the patients indicated still there were some compliance issues and problems during eating which were pain related conditions. It was mostly about the habit of eating, some hard and chewy foods and restricted oral hygiene measures that remain continuously throughout the time of the treatment.

I can eat without problem most of the time... I have adapted to the brace very well and my problems are reduced to minimum. But my case was difficult and my teeth were very irregular so I have to be very careful... D 17 FF.

When I place it recently, it was not like that. I have eaten just two bites of "yaprakh" and the band came out...then with the experiences I realised how to eat safely if I want... avoid the hard food and do not eat it because it hurts me when I eat it... I have to brush it anytime and everywhere and at any circumstances... L 11 FF

Still I can't eat hard food like apple and carrot... chicken meat particularly the breast is difficult because it is stringy and stuck with the brace and the teeth and I have to remove it quickly. It mostly get stuck with that part of the brace which is on my palate. There is no pain now, just when the food gets stuck it makes eating unpleasant... M 15 FF

Now I am about to cope with it but still I can't eat hard food and before the brace I had several snack outside but now I can't...I can't chew the food properly now so I am a bit slower and need time to finish the meal... Sh 15 FF

For the patients with a removable appliance or with retainers most of these problems were absent because they could remove the appliance before eating and eat normally. However the continuous removal and insertion of the appliance for them was one of the most common difficulties. They have to remove and insert it before every meal and snack and for those with transparent retainers for the coloured and hot drinks.

When I had the fixed one, after one month my eating started to be ok I could eat most of the food. But now with this one I have no problem and I can eat every things. I don't have any pain now but I have to remove it every time during eating. When I am at school I can't eat or I must go somewhere to remove it secretly or sometimes I try not to eat anything at school...Sh18 RF

I don't eat anything with it, now I just use it at night but at the start I wore it at daytime as well. It was uncomfortable, I had to remove it at every eating... I am allowed just to drink water with it, no tea, no coffee, and nothing else, actually I don't have any problem with those drinks but I don't do that just not to change its colour... Z FR 29

5.5.5 The impact of routine adjustment (activation) of the appliances on eating

Most of the participants called this procedure “tightening”. According to the reports of the participants, the adjustment brings back some of the earlier difficulties. In most of the cases, it eating deteriorates again after it has been in a period of remission. There were different reports from the patients about the cause of the difficulties and its relationship to eating.

Pain, again, was regarded as the most important cause of uncomfortable biting and chewing. The intensity of pain was not the same following every session, sometimes it reached a high level similar to the first week after placement. In contrast, after some adjustments, the pain was at a minimum level and it was hard to differentiate between before and after the tightening.

I have had the brace placed recently, I have had just one tightening and the pain was not like the first days after placement but still there was some pain. Therefore I started to have soup and soft diet again... K 25 FF

It is the case also during the tightening, the pain worsens, or sometimes the orthodontist forgets to cut the wire at the far back completely, still a sharp point remains which impinges my cheek inside during eating ...L 11 FF

It depends, sometimes it is good and sometimes it is painful. Sometimes the wire has some sharp end at the back and penetrates my cheek inside during speaking and eating

and I have to go back to my dentist the next day just to cut it. Some of the activations particularly at the beginning was painful and returned the pain to me just like the start of the treatment... my eating started to be difficult and I had soft diet again because biting and chewing were difficult...D 17 FF

For some of the participants it is an easy procedure and they can adapt to eating quickly. Their experience in dealing with these difficulties is a major factor in overcoming the eating problems easily.

When I do the tightening of the brace, the pain rises a little bit but it goes to normal quickly, I just try a soft diet at that time, however the pain is not like the first time... Z 25 FF 19

I have pain during activation, especially those times when he puts an elastic all around the brace. I feel my teeth going to be squashed together, but it doesn't take so long and I have adapted to it more than before. This is also difficult but nothing is like the first days, now I can prepare myself because now I know what to do because of experience... N 24 FF

On the other hand some of the patients related their difficulties during activation to adding auxiliaries such as wire or elastics to the inserted appliance. Furthermore, performing a surgical procedure in an adjustment visit was regarded as another cause that makes eating more difficult.

When one of my tooth was still inside my palate and my orthodontist tried many times to put the wire in a right position, usually after that I had pain in that area. I think because it was injured and eating became difficult a little bit. Two or three meals after that some types of breads and meats were difficult because they were chewy and their grinding were not easy. However, the other types of foods were normal...K 24 FF

My orthodontist has given a set of elastic to be used daily by myself. He asked me to keep the elastic inside even during eating. Actually I have no pain but I can't open my mouth easily and the foods get mixed with it...D 25 FF

After the activation particularly when they wanted to expose my teeth inside my palate, they made a surgery and then attached elastic and wires with it. Every time when they change the wires I have pain and eating become difficult then. When I eat some food particles goes between the wire and very difficult to clean... Sh.19 FF AFG

5.5.6 The Impact of Bracket Debonding or Appliance Breakage on Eating

In patients with fixed appliances bracket debonding may take place during the course of treatment. Debonding mostly takes place at the beginning of the treatment due to the novelty of the situation, not having prior experience and continuing to eat in the same way as before having the appliance. Bracket debonding can affect the patient's eating or interrupt their eating. On the other hand eating was regarded as the main causes of debonding which happens mostly with hard and sticky foods. This also included breakage of other accessories such as band loosening, and fixed anchorage breakage (transpalatal arch or Nance arch).

At the beginning, a couple of the brackets have fallen off at the time of eating, because it was new and I didn't know how to eat in a right way. I did have to not eat hard food, as small mouthful as possible and be careful during chewing... now it is ok... B 11 FF

Always I had one bracket which debond. That one debonded several times, it is the one at the back tooth, I always keep eye on it but it falls off I don't know why. It really bothers me. I have to eat very carefully and at the start my eating was very slow...

When the brace was recent I hadn't had enough experience and after eating some "yaprakh" the molar band came out with the food and I swallowed one of them. At first, I haven't realised but then I looked at the mirror and surprised that the band is missing. I really scared because I have swallowed this metal and it is in my stomach. I was afraid to get something bad... L 11 FF

After experiencing bracket debonding the patients tried to be more cautious during eating and avoid those foods that had caused previous bracket debonding such as carrots, different types of nut, chewing gum and chocolate bars.

Every kind of nut, apple, cucumber, carrot should not be bitten and have to be chopped to smaller pieces or have to be eaten very cautiously so as not to debond the brackets. You should not have anything with bite... D 25 FF

Until now none of them has fallen off but really I am worried about that. These metal pieces are dangerous for my stomach and intestine. I try to eat very slowly, and not to eat anything hard. Actually I am very careful not only during eating but for the other things as well... K 25 FF

I can't eat hard foods because of the pain and fear of falling the brackets off... I don't know it may fall off it because this had happened before... Sh 14 MF 20

Sometimes the debonded bracket or loosened molar bands interfere with eating by its movements and impinging on surrounded soft tissue.

For two times the bands came out, at first it was just movement and impinged my gum during eating especially chewy foods. Finally, it came out completely when I had a chocolate... Rs 21 FF 16

At the beginning when one of the back brackets debonded and was movable. When I had eating it was moving and hurt my gum and I abandoned that side during eating and used just the other side. I was really afraid to swallow it when it falls during eating... S 18 MF

5.5.7 Food selection and limitation

5.5.7.1 Soft diet

Soft diet was a term that described by most of the participants and it includes all foods which were soft or watery in texture and need less masticatory action to make the chewing and swallowing process easier. Selection of such kind of foods was mostly seen during the start of the treatment and sometimes after the activations. The most common cause for shifting to this kind of food was pain in the dentition.

At the start my staple food was soups, but now only at night when I feel I am hungry, I prepare a soup. Other than that I can eat normally... now I can eat rice but it must be soft, I can't eat the hard one... H 19 FF

I had just soft things so as not to have pain, I couldn't eat the hard food by any means and if I have pain any time I will go for soups. When my orthodontist changes the wires or elastics, the pain appear again and I have to eat the soup again... H 12 FF

It would be difficult if I eat like before. The wire weakened the force of teeth and I had to have just soft foods. Still I have those foods but only after the tightening because I have some pain. Now we have become more familiar after the activation day we cook a soup at once... L 11 FF

I have just soft food for two or three days and then I adapted to the situation of the brace... I couldn't bite; all of my teeth were tight and I had pain in all of my teeth...Rs 21 FF

Different ways were used to provide a soft diet either by different kinds of usual soups, changing cooking conditions of some of the foods (either by adding more water or increasing its cooking time) and drinking juices or using a juicer instead of eating whole fruit.

The meals of my family member differ from my meal, the cooking condition of my foods is different. It needs to be overcooked... H 19 FF

The meat has to be overcooked and I have to make it in a very small pieces then I am able to eat it... H 16 MF

Sometimes I cook my food and I try to overcook it so as to make it easier to eat. Besides that, my mum at the start of the treatment always prepared a soup for me. Still sometimes when I feel hungry I go and prepare a soft food like "Muhallabi" or other stuffs...D 17 FF

For the fruits I always use the juicer to prepare juice of the fruit or sometimes make it as a small pieces and then eat it... H 19 FF

Sometimes patients have to go for soft food even when they did not desire these foods because there were no other choices and they have to accept the reality of the situation. Sometimes the dislike was because some the soft diets are served to the sick people by Kurdish population.

My friend said you have to eat just soft food, really I don't like such foods but I had to go for those foods because there was no other choice and I couldn't eat the other types of foods... M 12 FF CFG

Soft food was just at the beginning of the treatment and now it is reduced. It was not my favourite but I had to go for it...Sh 15 FF

At the start I had to just eat Shorba just like the sick people... Sh 15 FF M

I really don't like Shorba because I am not sick... 12 FF CFG.

5.5.7.2 Sticking of different kinds of foods to the orthodontic appliances and its impact on eating

Sticking of food debris and particles was a further problem that faces patients during the course of their treatment. Orthodontic appliances act as a food retentive factor. This accumulation and adherence of different kinds of food to the orthodontic appliances imposes its effect on patients eating. According to reports of the participants, sticky food like chocolate, fibres of meats such as chicken breast and skin and fibres of some fruits and vegetables were most liable to get stuck to the orthodontic appliance.

Mostly meat chicken or lamb was difficult to chew and most of the time its fibres remain on the brace. This made to avoid these foods even though I like them very much. Also I had some problem with some fruits like watermelon, peach and few vegetables as well... The sandwich also difficult because when I bite small parts of the bread stuck on it... now I don't have chewing problem but the stickiness still problem therefore meat still difficult to eat or it must be in a very small mouthful... A 20 MF

Mostly the skin of some fruits and meat fibres stuck with the brace especially the back area, but I always clean it. I don't eat chocolate also for the same reason... B 16 FF

The meat is stringy and the fibre always stuck with my brace, it bothers me but what I do? After eating I just go and clean it... Sh 14 MF.

Stickiness of food could create an interruption in the patients eating and sometimes brings embarrassment when they were out with friends or people other than family members.

Meat pieces mostly go between my teeth and I have to remove them quickly... sometimes chocolate and chocolate bars remain on the teeth and the brace. I really don't like this but still I eat them... when something stick to my brace I feel shy to eat in front of others... H 16 MF

After eating immediately I clean my brace and I use interdental brush, this one is really useful and can clean it easily. If I am in the relative house I feel shy to run immediately so I use my lips and tongue even my hands to remove the stuck things and when returned home I will do my brushing.... Sh 25 FF

For some of the patients the degree of stickiness of food was high and extended to a level whereby they did not continue eating after the effect of the stickiness interruption. Sometimes they have to immediately clean or brush their teeth to remove the food particles on the appliances or are stopped from further eating even if not full.

The fibre of meat stick with my teeth and my brace and I have to remove it quickly, it mostly stick to my palate wire and I have to get rid of it very quickly because if don't, I can't eat anymore. Sometimes I give up from eating and I am still hungry... I don't have pain now but the stickiness of the food with brace makes eating unpleasant... M 15 FF

The meat is stringy and the fibre always stuck with my brace, it is bothering but what I do? After eating I just go and clean it... Sh 14 MF

Its cleaning is really annoying. I have to go immediately after eating to brush it. Sometimes when something stuck to the brace I don't like to be seen by anyone. This make me sometimes to eat with closed lips or hide it with my hand... when I am eating outside with my friend I try to give up eating earlier and run to clean it... Rs 21 FF

When I am at work I always try to have a clean brace without any food being stuck to the brace. Because for some people this may be disgusting. At the office I have got brush and tooth paste after eating I go immediately and clean it. I try to finish my eating earlier so as to be able to clean before they finish.... if I don't have my brush I never eat outside... S 25 FF

5.5.7.3 Hard and Chewy Foods and their Impact on Patients during Orthodontic Treatment

Hard food types was one of those phrases that was repeated several times during the interviews and focus groups discussions. Almost all participants expressed this phrase. Those sort of foods were negatively described by the majority of the interviewees and were indicated as one of the biggest challenges for patients with orthodontic appliances. Using these words repeatedly is likely to be related to the experiences of the patients with such kind of foods, the instruction of the orthodontist and the advice of others with or without orthodontic appliances.

Chewy food was another term that was described by participants on more than one occasion. They report problems with it during chewing and swallowing particularly at beginning of the treatment due to the initiation of the pain. In the later stages of the treatment hard and chewy foods were still difficult to eat and they have to change the way they eat those foods. Furthermore they were well known by both orthodontists and patients as the main cause of bracket debonding and as a source of pain exacerbation respectively.

Hard food is very difficult to eat, after my pain reduced later on, I wanted to eat meat I found out it was also difficult to eat because it was chewy and I fall off one of the bracket so I think always I have to be careful during eating such foods... Sh 25 FF

When you want to bite or chew those foods, you realise then you are unable to cut or grind the food, you think your teeth are blunt... Z 25 FF

If any food be hard or any other food that need to be cut by the front teeth like some nuts, sandwiches, pizza, apple, cucumber... I can't bite them with my front teeth I have to chop them it smaller pieces...K 24 FF

Yes, it was like that, when I wanted to chew the food it was difficult. Due to the pain in my teeth, I couldn't exert force on the teeth and was unable cut down the food.... S 18 MF

According to the report of a few of the participants, the first question that the orthodontist asks the patient after debonding was “have you had a hard or chewy food?”

Hard foods like nuts and sunflower seed, also chewing gum are difficult. When I have them, my lips will be injured and it is painful. If I would to eat them, it is just like a dangerous adventure. I mean it brings pain to me or make those things to fall off and I have to replace it again and this is need a time. Always my orthodontist blame me why I have done that, he would say you definitely have eaten a hard food. Sometimes I can't eat some of those things just because my dentist would criticise... N 24 FF

The first thing that my orthodontist instructed me was to not eat any hard foods with my brace because it will debond the brackets... H 16 MF

At the beginning of the treatment, one of the brackets fall off, the next day I went back to my orthodontist. When he saw it he suddenly said it is because you have eaten a hard food. Actually the food was not so much hard but I don't know why it happened... H 20 MF AFG

5.5.8 Changing Eating Habits during Orthodontic Treatment

It is obvious that everyone has his/her style of eating and always follows that pattern. This pattern will change according to the culture and tradition. In addition, the habit of eating changes according to the personality, types of the food, medical status and sometimes it depends on the venue of the eating.

Orthodontic treatment is mostly carried out in the adolescence period which is regarded as a very critical time for the growth and development. Any change during this time may produce its influences in adulthood and any deterioration in this period could impose an impact on health and well-being afterwards. Adult patients also faced changes in eating habits during treatment but this may have less of a long term effect.

From the beginning of the treatment until the end and even after the end of the active treatment and during the retention period, several sorts of eating habit changes will take place. These changes were mainly interrelated and would depend on many factors such as personality, age, place, time and type of the treatment. Most of the changes were more obvious at the start of the treatment when most of the difficulties and pain starts. However, some of the changes continued throughout the treatment time although with different magnitude and intensity between patients.

These habits tended to commence at the start of the treatment but then continue to a lesser degree during the remaining treatment time. This also depended on the type of the foods being eaten, with impact mainly limited to the hard and chewy foods which exert more force on the dentition and

need greater chewing and biting forces from the muscles of mastication. Smaller pieces of food reduce pain on the dentition. The stickiness and stringy nature of some foods also forced the patients to follow particular habits during treatment. The main impact was an increased desire to clean and remove the stuck foods, especially when they were eating outside with others.

According to the report of patients in both the interviews and the focus groups several eating habits changed which can be categorised as follows:

5.5.8.1 Chopping the Food into Smaller Pieces

This habit tended to start at the commence of the treatment to decrease the pain associated with the insertion of the appliance and reduced the frequency of the brackets debonding. This process made the incising of food unnecessary which was painful and increases the chance of anterior bracket debonding. Furthermore it decreased the chewing force which again reduces pain in the posterior teeth and reduces bracket debonding. Some of the participants reported that they did not incise sandwiches and wraps but instead tore or cut them into smaller pieces for chewing. Apples, carrots and some kind of nuts were repeatedly described by the participants as they can eat these foods in smaller pieces.

If I eat like apple, carrot, cucumber I have to chop it into very small pieces so as not to make my teeth tired with biting and chewing which was very difficult... L 11 FF

I realised that gradually I become familiar with it. I have to cope with it because it becomes part of my body and fixed inside my mouth. My mother encouraged me a lot and always asked me to eat; she always cooked special soft meal for me. As I said before I had soft diet at the start like soup and yogurt then I have chopped some other food to smaller pieces which made my eating easier... R 21 FF 3

As I said I have to chop the foods into smaller pieces, I have to eat very carefully so as not to make anything bad to the brace. I can eat sandwiches like before also I have to cut it with hand into a small mouthful and then eat it... S 18 MF

5.5.8.2 Using Smaller Mouthfuls

Another eating habit change is having a small mouthful to minimise the process of chewing and so that the food can be swallowed easily.

Sometimes for example last night I chopped the fruit with knife into smaller pieces and then able to eat it...now I eat slower, and if I have rice I have to squash it with the spoon and then eat it in very small mouthfuls, I can't eat it easily like before... H 19 FF

Before having this brace I had large mouthfuls and I could eat it easily but now I make the mouthful very small to be able to eat it. I am on diet actually and the brace is helping me in this regard... L 11 FF

Before I was able to open my mouth as wide as I want but now it is impossible, so I can't have large mouthful, I have to make it very small, I will break the hard foods, crush it first and then eat it. I have to help myself with hand... N 24 FF

I have to have a small mouthful so as to be able to chew it comfortably and to not allow it to stick to the brace... MF CFG

5.5.8.3 Low Speed of Eating

The change in eating speed was cited by most of the participants. They reported that the eating speed reduces due to the longer time needed for chewing. Some of them liked this habit change due to the inability of the teeth to grind the food properly. Furthermore eating slowly enabled them to manage the mouthful in easier way and reduce the incidence of stickiness which was one of the important causes of slow eating.

It is slower now, I realised that I am the last one who finishes the meal, beside this I eat less than others. Parts of it stick to my brace and this affects me very much. Imagine I had this brace inserted 3 years ago but I don't think I have ever been stuffed particularly when I eat outside... S 25 FF

Now I eat slowly. Because the food stuck between my teeth and the brace, I can't eat chewy foods and I have to retain the mouthful for longer time in my mouth and chew it more than often, because I feel my teeth are wobbly now and I can't grind it very well, my teeth can't force any more... P 19 FF

I have noticed that I am slow, all the time my family asks me to hurry up and finish the meal and then I have to eat very quickly. Therefore, sometimes I have to finish my eating earlier... Sh 14 MF

Some of the patients reported that they were the last person who finishes their meal. Sometimes if they were in places other than home or with other people they had to give up eating before being full. This was mainly to not give a bad impression about his/her eating style.

I can't eat like before anymore; my eating speed changed and become very slow. Always I am the last one who finish... they finish their eating much earlier than ... H 19 FF

I was slow before and now I am a bit slower. Sometime my family make fun of me and they say you're eating a lot but actually I eat less but slower. When I am invited to my relative house, I try to eat less and finish it earlier even if not full. I think it is better to finish it earlier because all of them have finished... N 24 FF

5.5.8.4 Retaining the Food for a Longer Time inside the Mouth

Some of the participants reported the retention of the foods for a longer time than usual or chewing the food for a longer period. This habit also started at the start of the process and remained continuous throughout treatment.

Besides being very slow in eating, I retain the morsel for a longer period in my mouth so I finish my eating later. I think this way may be better because I can chew it adequately and swallow it with less difficulty... Sh 15 FF

At the beginning, it was very difficult, it was not like before, you can't chew the food properly and I have to swallow it as it is and it was difficult. But now it is better, I can chew it if I keep it for longer time but still it is not like before having the brace...H 12 FF

According to some of the participants this habit was regarded as a positive shift which makes the food easier to swallow and helps the later process of digestion.

Now I chop most of the foods to smaller pieces, I have smaller mouthfuls and keep the mouthful for a longer time in my mouth to chew it comfortably. Also I always avoid having the hard foods... Z 25 FF

I can't swallow it, but if I can't chew it easily either I have to swallow without adequate chewing (intact morsel) or have to retain the mouthful for longer time in the mouth. This one I think make the food more wet and softer which can be easily swallowed.... D 17 FF

Sometimes when I can't chew properly I swallowed the food as it is, but now I keep it inside my mouth for a longer time so as to chew it adequately and swallow it easily... Sh 14 MF

5.5.8.5 Eating Less and Weight Change

Some of the participants also indicated that the amount of food they were eating decreased and related this to weight change. This feature was also more obvious at the start of the treatment and later on when the difficulties become less, the amount being eaten improved and weight was gained and returned back to the level of before the appliances were placed. Losing weight was controversial between participants, for some of them it was positive because the appliances helped

them to reduce the amount being eaten. By contrast for some others it was negative as they were already thin and were worried about losing further weight. These arguments mostly expressed by the female participants.

I become thinner, as I said when I go in front of mirror and look at myself as see I become thinner....some people like to be thinner but I am already thin and I don't like to be thinner. I like to gain some weight... H 19 FF

I have changed a lot lost my weight, my weight was 73 kg and now I am 65 kg. I have lost a lot... N 24 FF

Actually I am on diet now and I realised that the brace is very helpful in that regard. It is very good for losing the weight because it prevents you from having some of the foods and this is good for me... Sh 25 FF

Yes, I have lost weight, when I first put the brace on, it was (Ramadan month) and I was fasting, beside this I could not eat like before, mostly I had a soft diet, so I think it was the cause of my weight loss. I think it was just the first two months but now it is better... R 21 FF

5.5.8.6 Using Hands, Lips and Tongue at the Time of Eating

Some of the participants indicated that they have noticed they use their hands, lips and tongue more than usual for removing those food particles and fibres that stick within the appliance. Other participants reported using their tongue and lips were to grasp the food during the first few days after insertion so as not to bite it with their anterior teeth due to the pain.

My front teeth cannot bite or cut anything, so for some of the food I have to grasp it with my lips rather than the teeth. This is mostly true when I eat banana and ice lolly... K 25 FF

When I eat I feel most of it stick with the brace and then I have to remove it with my hand and my tongue. You know this is fine if you're at home but outside it is somewhat difficult... K 25 FF AFG

5.5.8.7 Using their Hand to Hide the Appliance during Eating

Using their hand to hide the appliance was also reported by a small number of the participants. This habit happened mostly when they were with other people during eating. This habit also occurred during speaking and laughing.

It is not comfortable when you eat with others to let the brace be obvious, I eat always with closed lips, even I eat at home just like that and I am afraid to remain like this

even after the treatment. Because eating in this way is really annoying and I can't swallow the food easily... H 12 FF

Now I don't speak too much during eating, I have to hide my brace with my hand when I speak because sometimes food particles or saliva droplets escape from my mouth. This is really embarrassing... D 25 FF

Most of the time when you would be invited or eating outside home, you have to hide the brace with your lips or when you speak or laugh put your hand in front of it just to hide it. I am afraid I have food stuck on the brace and they may feel it is disgusting... S 25 FF

Feeling embarrassment was another reason that patients liked to hide the appliance during eating or speaking.

It is not comfortable when I eat always food stuck between my brace and teeth therefore I never speak during eating, I feel shy when I respond to them and I always use my hand to hide my mouth... H 12 FF

5.5.9 Social Relationships and Eating with Orthodontic Appliances

Social activities in relation to eating was one of the other subjects which was described on many occasions. Different socially related issues emerged from the participants which were also interrelated to other factors such as the time of the treatment, habit changes and the appearance of the appliances. The social relationship to eating included different categories which are described as follow:

5.5.9.1 Eating with Others

This topic included eating with friends, colleagues or even unknown people. Some of the participants indicated problems when they were eating with others. They needed to be more cautious in eating and tried to make the appliances less obvious which makes them nervous. Not only were people more self-conscious in social situations, but such situations highlighted the limitations caused by the brace, as people were unable to eat the special (as opposed to “everyday”) food that had been prepared for the social gathering

I can but it is not comfortable to sit with the for eating because you can't eat all kind of foods like them... you have to eat something special, eating very cautiously not to allow anything to stick with my brace. ... L 11 FF

It is somewhat difficult. Sometimes you eat with the other people who can eat easily and I have to eat in my way and this is bothering me. I feel that they gaze at me. I can't

have some coloured drink and foods because it appears on the elastics of the brace and this is not good... S 25 FF

You can't eat with your friends outside because it is cleaning after that is difficult, you have to go to clean it after eating at once. Sh 25 FF

It is usually uncomfortable because I used to have food stuck with my brace, somehow I feel shy when I eat in front of them, and they always ask me how I can eat with having such thing inside my mouth... H 16 MF

5.5.9.2 Eating Alone

Some of the participants reported their preference to eat alone particularly at the start of the treatment. This was due to the inability to eat like others or because they give up before finishing the meal or feeling full. Most of the participants were happy eating with family members or those who have orthodontic appliances because they were more aware about the problems than the other people

I have eaten with my friend and one of them got brace as well. I always liked to eat with her or sometimes to eat alone... B 11 FF

Sometimes it is difficult to go outside to eat. At home I don't have so much problems but in the other places, it is not good to be seen with some food stuck to the brace. For some people it is not nice and this makes me to not eat some foods and to be very careful...18 S MF

5.5.9.3 Eating Outside the Home

Outside eating activities include eating at school, the workplace or restaurants. At school the children tried to reduce their eating or sometimes to not eat anything at school. Inability to clean or/and brush the teeth was one of the most common causes. For some of the adult patients eating at the workplace also changed by having foods which were easier to eat and less likely to stick to the appliances. They indicated a decrease in snacking during work due to the cleaning and brushing demand. Finally most of the participants reported that the frequency of eating at restaurants decreased during the time of the treatment. The other common excuse for decreasing the eating outside home was embarrassment when eating with others and due to having appliances.

No, my eating outside decreased, because you can eat anything that you like properly and eating already become difficult. Other than this you would have to run quickly after eating to clean it... Sh 25 FF

At first it was very difficult to eat outside, even the smallest thing. Usually I eat snack food outside but it is difficult to eat them normally, because I have problem with biting.

I tried to eat them normally like before but two of the back brackets were fallen off and increased my problems. Therefore, for about one month after that occasion I had no eating outside at all. R 21 FF

Sometimes it is difficult to go outside to eat. At home I don't have so many problems but in the other places, it is not good to be seen with food stuck to the brace. For some people it is not nice and this makes me to not eat some foods and to be very careful. If it was feasible I have to go and clean it or if not using my tongue to clean and remove the stuck foods. This is really difficult and annoying me and sometimes injured my tongue...18 S MF

I go to restaurants, but I am more comfortable at home because I can go anytime to look at my brace with a mirror to be sure nothing bad happened during eating. But when I am outside I feel very embarrassed to go to toilet straight away after the meal to see my brace and clean it. ...N 24 FF

5.5.9.4 Rejecting an Invitation or Offered Foods

Uncertainty about an invitation or offered foods was also related to the social activities during the time of the treatment in which they have to reject some invitation or reducing visits to relatives and family. This was mostly due to the difficulties with eating and fear of being offered foods that were difficult to eat.

When I am in my office they bring some foods mostly sandwiches, I say sorry I can't eat these...I always say this but sometimes they may think I am caring for too much. Fortunately, now they realised that such type of treatment need an extra care and preservation...S 25 FF

They brought some hard foods like some biscuits and sweets and other things like that, I have to make it in smaller pieces with my hand, really I feel shy to do such thing in front of others, and therefore I put it down and say sorry I don't like it... D 25 FF

There were also some situations when participants refused to eat an offering of food especially when it was after brushing. This occurred mostly at night when they have already undertaken their final brushing and cleaning and did not want to repeat this.

It depends, sometimes I rejected to eat because just had brushing - I get bored with brushing. And sometimes I will go for it and do brushing again. This mostly happens after eating when they bring fruit or sweets and I will say sorry I don't like to eat, just had brushing... Sh 15 FF

I have faced such situation, it happened a lot when especially at night after supper, they bring something to eat, if I like it very much I will eat it and then go and brush my teeth again. However, sometimes I don't eat and the reason is just brushing... H 19 FF

When I am outside at the relative's house, and recently brushed my teeth or sometimes because I do not have my toothpaste and toothbrush I don't like to eat it. This situation also happened sometime when I was at university... Rs 21 FF 16

5.5.10 Enjoyment of Eating

From the participants descriptions it was clearly visible that the enjoyment of eating was jeopardised by the treatment to some extent. This issue is mostly time dependant and mostly happened at the beginning of the treatment. However this was continuous throughout the treatment to a lesser degree.

5.5.10.1 Eagerness for Eating

Losing the desire to eat was noticed by most of the participants particularly at the start of the treatment due to the pain and inability to eat properly.

At the start of the treatment, sometimes there were different types of food and I liked to have them but I couldn't. So I just stuffed myself with tea and biscuits, it was really boring... D 25 FF

Since I have placed the brace I don't like to eat and there is nothing left to enjoy in eating... when it was placed recently I was not pleased with eating, I have not wished to see the table cloth because I was hungry and could not eat properlyt... N 24 FF

The brace makes me not to wish or like eating because I know some problems are going to start. By contrast before placing the brace I liked eating... H 19 FF

Inability to eat food normally, like before the appliance was inserted or stickiness of the foods to the appliances were other reasons behind losing their eagerness to eat.

Before placing the brace somebody told me you are going to disfavour some kinds of food or you don't like to eat then anymore. Mostly I like to bite the fruits, and eat it normally, but now I have to chop it into smaller pieces. My view towards those foods has been changed, even sometimes I don't like to eat them... R 21 FF

Now the situations have changed, in the past before placing the brace I was always happy with eating and pleased when I saw the food on the table cloth because I didn't

*have any problem with eating and there was no food stickiness and slow eating... S 25
FF*

5.5.10.2 Not Eating their Favourite Foods

Some of the participants avoided having their particular favourite foods because of the appliance and they missed those foods. They could not have those foods because of the risk of initiating problems like debonding, stickiness and pain.

Because before placing the brace I liked different kind of bread and had it at every meal. Now I can't eat it because some of them are hard and the others are chewy, so I can't eat it easily and it brings pain to my teeth, sometimes I just eat the softer part of some of the bread and eat it... D 17 FF

Generally I have problems with meat particularly chicken breast which I like mostly. I can't eat it because it gets stuck between my teeth and the brace particularly at the beginning of the treatment and when you eat quickly... S 25 FF

I like "Yabrah" and it is my number one, but the brace do not allow me to eat it like before having the brace... L 11 FF

Drinking also can be regarded as one of the causes of reduced enjoyment by some of the participants who avoided some of their favourite drinks. The most common reason for this was because the colour of the elastics or the white brackets can be changed by some of the coloured drinks like tea and coffee. Whereas others avoided hot drinks due to the instruction of the orthodontist to preserve the force of elasticity of some of the elastics or cold drinks due to having dentinal hypersensitivity after some dental operation like interproximal reduction for creating spaces for the orthodontic treatment.

Now I have got very sensitive teeth, I have problem with hot drinks, when I drink it I have pain...However if the water is too cold, it brings pain as well. I think it is due to the brace or because I am brushing my teeth a lot and using toothpaste too much... D 17 FF

*I am not using coloured food and drinks at all so as not to change the colour of my brace. However it is very difficult to keep it white even I always clean it regularly but it is still yellowish. I have chosen this type of bracket just because it is white and not obvious but it was just at the beginning and gradually the colour has changed... FF
AFG*

Now I don't drink tea and coffee a lot because it changes the colour of the elastics which is something I don't like.... I can't have too cold and too hot drink because it is painful, I had such problem also before inserting the appliance but after insertion it has been increased... MF CFG

In contrast for some others they can still have their favourite foods and enjoy eating them even though they were still difficult to eat.

I like "Kufta" and still I eat it, even there are some hard foods inside like nuts but because it is "Kufta" I eat it... M 15 FF

I like toffee and still eat it but in different way by keeping it for a longer time in my mouth and have a mouth rinse after that immediately. However it is lesser than before... H 19 FF

5.5.10.3 Taste change

Taste change was also reported by some of the participants. The change of the taste related to either to food remnants on the appliance or the elastics which have been replaced recently.

I think the taste changed a little bit, sometimes I feel a sudden bad taste come to my mouth and mix with my current eating and then disappear. This is bothering me a little bit...A 20 MF

Sometimes when the elastics being changed, I feel a bad taste... B 11 FF

The taste has not changed, the only thing that I can't eat is chewing gum, I am afraid to stick with the brace. The first day after the activation, a strange taste can be felt in my mouth which may be due to the new elastics and wires. I feel this is only at the first meal after the tightening... K 24 FF

Other participants related the taste change only to the start of the treatment when they only think about the pain rather than the real taste of the foods due to the difficulty in chewing the food properly or thinking about some consequences of the problems.

The taste changed and it is not like those tastes that you have used to it. Believe me now I eat fruits and I can't feel its taste. You can't chew it properly and have to swallow an intact morsel. If you do not chew it properly you can have its real taste... before the brace, everything was tasty in my mouth and it is not now.... K 25 FF

At the first week, the taste had been changed, and all things became tasteless, because the pain and the food remnants I have not yet had a chance to think so much about the taste of food... R 21 FF

I think the taste is no longer like before, it is not 100% like before, because always you have to eat cautiously and be careful to not debond the brackets, you think about the brushing and there are several heavy metals inside your mouth so you can feel the real taste... Sh 25 FF

5.5.10.4 Eating Cautiously

Eating cautiously was another habit that some of the participants reported. This factor was also interrelated with other themes. At start of the treatment participants were worried about the brackets debonding. Participants also had to be careful during eating so as not to allow the food to stick to the appliance or to hide the appliance, particularly when they were with friends or eating outside.

Now I have coped with the situation, in most of the time when I eat with other I want to give up my eating earlier not to give a bad impression about my eating. S 25 FF

After finishing the eating I have to go to brush my teeth and I have to eat very carefully. I always worry and be cautious about my surrounding people and cautious about my brace to preserve it and keep it clean... S 25 FF

I feel shy when I eat with others and have to eat more slowly in comparison with them. Also I have to eat very cautiously to not make any of the brackets fall off... S 18 MF

5.5.10.5 Inability to Speak Freely during Eating

One of the other social related problem was the inability to speak freely during eating which was reported by a few of the participants. This problem was mostly seen during eating with other people and outside the home because participants were afraid of having food stuck to the appliance and giving a bad impression.

Now I don't speak too much during eating, I have to hide my brace with my hand when I speak because sometimes food particles or saliva droplets escape from my mouth. This is really embarrassing... D 25 FF

It is not comfortable, when I eat there is always food stuck between my brace and teeth therefore I never speak during eating, I feel shy when I respond to them and I always use my hand to hide my mouth... H 12 FF

5.5.10.6 Giving up with Eating before Feeling Full

Giving up with eating was mostly related to the interruptions that happen during eating such as stickiness of food to the brace or the reduced speed of eating, meaning participants needed to stop earlier either to be finished with others or to go and clean the appliance, particularly when they were outside or eating with others.

I have faced such a situation before feeling full I have given up eating because I thought it was not nice to continue eating when all finished. They may say this girl is greedy... H 19 FF

Yes, I have noticed that I am slow, all the time my family asks me to hurry up and finish the meal and then I have to eat very quickly. Therefore, sometimes I have to finish my eating earlier... Sh 14 MF

The fibre of meat stick with my teeth and my brace and I have to remove it quickly, it mostly sticks to my palate and I have to get rid of it very quickly because if don't, I can't eat anymore. Sometimes I give up eating and I am still hungry... I don't have pain now but the stickiness of the food with the brace makes eating unpleasant... M 15 FF

When I am eating outside with my friend I try to give up eating earlier and run to clean it... Rs 21 FF

5.6 Discussion

5.6.1 Introduction

In dental studies the use of qualitative methods has dramatically expanded and has been implemented in different kinds of studies (Feldmann *et al.*, 2007; Griffiths *et al.*, 2008; Hyland *et al.*, 2009; Rousseau *et al.*, 2014; Wang *et al.*, 2015). Additionally in orthodontic studies this trend can be obviously seen and many more qualitative studies have been undertaken (Travess *et al.*, 2004; Mandall *et al.*, 2006; McNair *et al.*, 2006; Abed Al Jawad *et al.*, 2012; Carter *et al.*, 2015; Patel *et al.*, 2016). A qualitative study conducted in Kurdistan-Iraq with two age groups of orthodontic patients was undertaken to expand our knowledge about eating difficulties encountered during orthodontic treatment and to explore possible age and cultural differences with this treatment. This intends to make the research more patient-based and to extract information directly from the patient's experiences rather than relying on the clinical skills of the orthodontists. Until now our knowledge about eating and ERQoL during orthodontic treatment is limited and mostly relies on clinical experience rather than research based information. Additionally the findings of the qualitative study can be used as a foundation for delivering dietary advice based on scientific evidence during the course of orthodontic treatment.

5.6.2 Methodological Considerations

Both face to face interviews and focus groups were performed in this study. Recruitment processes for the focus group proved more challenging than for the interviews. The percentage of refusal to

participate in the focus groups was very high in comparison with the interviews (Table 5.1). The most common reasons given was feeling shy speaking amongst others and not having enough time. Despite the brief introduction about the idea of a focus group before commencement of the session, it was still difficult for them to understand the concept of the focus group. At the start of the discussion the participants thought that it was mostly like a question answering session. Therefore the researcher had to ask them about their experiences continuously rather than participants spontaneously contributing to the discussion. However, towards the end of the session the quality of the discussions improved because some spontaneous discussion occurred and counterpart conversation started between some of the participants. Therefore the conversation extended and some previous questions were repeated in different ways in order to receive more information and reach a point where no further new themes emerged.

During the recruitment process it was established that the use of functional appliances is very rare because the majority of the patients were undergoing fixed orthodontic treatment with a limited number of patients with removable appliances. Another cause may be due to the age for the functional appliance treatment which was most effective when started during active growth, which would be at the younger end of our target population.

5.6.2.1 Qualitative Study Topic Guide

The form of the topic guide mainly depended on the sampling strategies and the analysis of the qualitative data. In convenience sampling and purposeful sampling the topic guide is relatively stable and the data collection will continue without major changes in the questions. Changes in questions may be limited to areas which are either not relevant to the discussions or new themes which are particularly notable during data collection. Whereas in grounded theory, the technique which requires theoretical sampling strategy, the topic guide questions will be continuously modified according to emergent categories and theories (Coyne, 1997).

The topic guide was a tool used to guide the interviews and focus group discussions. The topic guide can be developed using the existing literature and researcher experiences (Campbell, 1999). One of the ways to deliver a fluent interview and discussion was by following pre-determined topic guide. In order to explore a wide range of information, a range of issues, even those which were not commonly expressed by the participants in the study by Carter *et al.* (2015) were also included in the topic guide such as weight change and taste change which came from the researcher experiences in orthodontic treatment. By using these guides it was found that these less common issues were also a source of concern to some of the participants. The topic guide for the focus group was derived from the findings of the qualitative interviews. Other activities were included

in the focus groups to encourage the participants to engage in active discussion, these activities included role playing and a short quiz game. This strategy helped the children's focus groups as it acted as an ice breaker and encouraged them to participate in the discussion. By this step the participants became familiar with topic of the study and the focus of interest which allowed them to engage with the discussion in an easier way. Furthermore it acted as a good tool to help participants introduce themselves to other members of the group. It is good practice to include brief information about the topic guide and methods used to construct the topic guide in publications, and some other studies give details of the ideas behind the topic guide and how its items were derived (Lam and Longnecker, 1983; Abed Al Jawad *et al.*, 2012; Carter *et al.*, 2015; Patel *et al.*, 2016). Carter *et al.* (2015) indicated the topic guide for the semi-structured interview was derived from a number of focus groups which were conducted earlier. Furthermore, Patel *et al.* (2016) used previous literature to derive the topic guide items and tested the topic guide with a number of orthodontic patients. Abed Al Jawad *et al.* (2012) used the suggestion and experience of a number of specialists and practitioners to establish important themes and then piloted these in four interviews. Using prior experience to inform the topic guide means the vision should be clearer and the researcher can have greater control over the quality of received information. In addition to that the background knowledge of the researcher was also another factor which can be used to guide the topic guide development and allowed the researcher to probe the emergent information more confidently. For example fixed transpalatal arch anchorage acts as an extra food retention because of its physical obstructions in the mouth. This problem is more familiar to an orthodontist researcher and therefore they can probe this problem earlier or include it in the earlier version of the topic guide. Debonding of the brackets is another problem that mostly happens during eating but sometimes a weak bond between the tooth surface and bracket base may be the reason for debonding rather than careless eating. An experienced orthodontist researcher can probe this problem more confidently because of having a background knowledge about this issue. However, relying more than necessary on background experience may transform the semi-structured interview to a non-structured interview and reduce the patient-based focus of the research (Rosner, 1982).

5.6.2.2 The Age Limit of the Participants

The age of participants who participated in the Kurdistan qualitative study was divided into two age groups, children (11-16 years old) and adults (17-25 years old). Orthodontic treatment is often commenced in childhood, due to the rapid pre pubertal growth spurt which occurs around this age range and makes some aspects of treatment easier. Therefore most of the other studies dealt with child aged patients for example Patel *et al.* (2016) interviewed 10-16 years children, Abed Al Jawad *et al.* (2012) and (Carter *et al.*, 2015) interviewed children aged 11-14 years old. Many other

studies recruited children of 11-14 years which may be the influence of CPQ which was constructed for this age group (Jokovic *et al.*, 2002; Jokovic *et al.*, 2005; O'Brien *et al.*, 2006; Locker *et al.*, 2007; Agou *et al.*, 2008b; Do and Spencer, 2008; Marshman *et al.*, 2010). Moreover, the CPQ items may have an influence on topic guide questions for the qualitative studies. As such most of the qualitative studies tried to include this age range to explore more about the related orthodontic difficulties and find more in-depth information from the age group most likely to be undergoing treatment. On the other hand, in the older age group (17-25 years old) this is a time when social activities and regular employment starts and this may bring further difficulties in the orthodontic treatment. Therefore, having as much as information about eating difficulties during treatment from the patients' experiences should allow patients to be better prepared prior to commencing treatment. Therefore by including these two age groups which covers most of the patients who seek orthodontic treatment should reveal age related difficulties, differences and similarities.

5.6.2.3 Sample Size and Selection

In qualitative studies it is crucial to select participants who can fulfil the aim of the research and therefore they cannot be selected randomly. As Morse and Field (1995) highlighted, the sample size must be adequate to generate sufficient data and must be appropriate by selecting the right participants who can enrich the study with their experience and knowledge. In qualitative studies one of the criteria for determining the adequacy of the data is data saturation which is a point where no more new themes emerge and it does not necessarily need to be statistically representative (Sandelowski, 1995). In the current qualitative study, purposeful sampling strategies were selected to select the participants for the study. Sandelowski (1995) also emphasised the use of such methods during qualitative data collection to find the maximum variation between the participants of the study (Coyne, 1997; Meadows *et al.*, 2003). At the start, data collection was based on the first draft of the topic guide, and after several interviews and preliminary analysis together with the research team, the topic guide was modified and used in the successive interviews (appendix E1). One of the important points that was considered was the stage of treatment at the time of the interview. This is because most of the participants indicated that at the start of the treatment most of the difficulties emerged. Therefore, to gain more reliable and not memory dependant information several participants were included who had recently commenced their treatment. Data saturation was felt to have been achieved after 29 interviews across both age groups and the interviews provided the core of the information collected. The other two similar studies on eating difficulties during orthodontic treatment involved less participants than this study, Carter *et al.* (2015) interviewed 14 participants and Abed Al Jawad *et al.* (2012) reported reaching data saturation after 10 participants. The number of the participants in this study was greater due to

having two age groups and the age limit of the children's group having increased to 11-16 years old. Whereas the two previous studies, the age of the included patients was restricted to 11-14 years.

5.6.2.4 Qualitative Analysis

Analysis of the qualitative data can be undertaken in many different ways and there are no correct methods for such analysis (Smith, 1995). Two fundamental and accepted approaches in qualitative analysis are the deductive and inductive approaches and they can be handled in different ways (Spencer *et al.*, 2003; Williams *et al.*, 2004; Burnard *et al.*, 2008)

Using a pre-determined explicit structure or framework is a feature of the deductive approach and the analysis will be performed according to those structures. This is useful mostly when the researcher is in the field and already has information about the participant's answers (Williams *et al.*, 2004). Such methods are flexible, quick and easy in application but have potential for bias because pre-established experiences and coded frameworks may lead the researchers to pre-determined analyses (Burnard *et al.*, 2008). In contrast, the inductive approach utilises emergent theories from the actual data as a means of analysis and does not rely on pre-determined structures. This method is useful when a phenomenon is not well known and is under investigation. Content analysis is an example of the first approach, while grounded theory is an example of the second (Williams *et al.*, 2004).

One of the important steps in a qualitative based study is how it is analysed and the need to be reflective about the influence of the researcher's prior knowledge and experience on their engagement with the data. In this project, the researcher has several years of experience in clinical orthodontics and this was likely to have an impact on both data collection and analysis; influencing for example what the researcher chose to follow up in interviews with further questions, and the patterns that they observed during the data analysis. However, having background information may be advantageous during qualitative data collection because the researcher can probe the questions more confidently. To reduce the risk of an orthodontic-only focus on the analysis supervisors with different perspectives were involved; a social scientist and a nutritionist. Analysis of the qualitative data was initially performed with the research team and their opinions and suggestions were taken in consideration during the data collection and analysis stages. This stage mostly increased familiarization with the dataset and topic guide modification at the earlier stage of data collection. The second analysis step was using a framework analysis (Gale *et al.*, 2013) which can provide a relatively flexible method for the researcher to organise his background knowledge on the analysis. This method of analysis allows a deductive approach to select the

themes in the transcript based on pre-selected questions, literature, theories or experiences (Gale *et al.*, 2013).

Framework analysis was developed by the National Centre for Social Research in the UK during 1980s (Ritchie *et al.*, 2003). This method can be used in deductive, inductive or combined approaches of analysis (Gale *et al.*, 2013). It can be defined as “when particular settings, persons, or events are deliberately selected for the important information they can provide that cannot be gotten as well from other choices” (Maxwell, 1998). Inductive approaches can be implemented in the framework analysis to determine the themes openly in an unrestricted way. However, combined deductive and inductive methods also can be used in framework analysis, which leaves a space to accommodate new, unexpected themes which may emerge from participants in a systematic predetermined way (Gale *et al.*, 2013). Therefore, whilst it is difficult for a researcher with previous experience of the subject of under investigation to avoid his influence on the analysis, this experience must be used in a way that does not override events but facilitates the process of analysis. Researchers can develop a set of categories which are known as “analytical frameworks” that can be used to organise the data. As such, framework analysis allow researchers to compare and contrast the data easily, either across all the qualitative data or within individual data. Moreover, the analytical framework and/or the analytical index act as a linkage between the data and the process of analysis and make the analysis process relatively transparent (Mays and Pope, 2000; Ritchie, 2003). Following such a procedure the researcher can consciously refer back to the data and make a comparison with the analysed data through the indices, framework and analysis chart.

Purposive (purposeful) sampling is an acceptable sampling strategy in framework analysis. This type of sampling is mainly based on convenience, homogeneity and maximum variation of the participants (Meadows *et al.*, 2003). Many qualitative studies in orthodontics have used framework analysis as a method for the analysis and purposive sampling as the method of choice for sampling strategies (Ryan *et al.*, 2009b; Abed Al Jawad *et al.*, 2012)

In the current study the analysis was performed on the Kurdish transcript rather than the translated one. This allowed the process of analysis to be conducted on the real verbatim of the patients rather than a translated transcript. Twinn (1997) found some differences in the emergent themes between the analysis of the same data in two different languages when the original data and the translated data were analysed separately. Whilst these differences were not significant, it was still important to ensure the study remains as patient based as possible.

There were several factors that enabled the researcher to familiarise deeply with the data. Firstly the language during the data collection was Kurdish which is the researcher's mother tongue language. This allowed easy probing of the emergent themes and fluent communication with the participants. Secondly, previous experience and clinical background in orthodontic treatment helped the researcher realise the difficulties and direct the questions more confidently. Lastly transcription of the all the data was performed by the researcher which required listening and playing back of the recorded audio files several times.

To enable the research team to have an insight into the process of data collection and analysis, several transcripts and the analysis of the qualitative data were translated into English by the researcher. The translated data and analysis was also checked by an independent Kurdish PhD linguist who was highly experienced in Kurdish-English translation.

Lastly, although the researcher participated in a course regarding analysis of qualitative data using the Nvivo software program (appendix I), this software was not applied to the analysis of the qualitative data because a) incompatibility of the Kurdish alphabet with the software and b) using the framework analysis which is mostly dependent on indexing and charting and can also be undertaken using other software such as Microsoft word.

5.6.3 Qualitative Findings

5.6.3.1 The Impact of the Time, Age and Patient Expectations during Orthodontic Treatment

Time was one of the important factors that affects patients during the course of orthodontic treatment and the impact of the orthodontic appliances on eating was not consistent throughout treatment. This was most obvious at the start of the treatment and shortly after adjustment of the appliances. In addition to that, it also included interventions which were essential for treatment such as some surgical and periodontal interventions.

In previous studies the impact of the time on the orthodontic appliance and OHRQoL has been demonstrated widely. The literature reveals that pain during orthodontic treatment is one of the obvious problems and some studies have linked pain with eating difficulties (Bergius *et al.*, 2002; Otasevic *et al.*, 2006).

During the first week after insertion orthodontic patients face the highest level of pain with different intensity from day one to day seven (Erdinc and Dincer, 2004). Bernabé *et al.* (2008c) indicated that eating is one of the most obvious daily activities which is affected by fixed orthodontic appliances. They reported that 9.5% of patients had difficulties with eating and 35% of those patients indicated severe or very severe intensity. According to the patient reports in both interviews and focus groups in the present study, most of the deterioration in eating happened

during the first week of the treatment (Figure 5.4). However, participants were not consistent in their reporting of the time period when their eating deteriorated most. The time interval that appears to be most problematic starts at the first day after insertion until one month or even a few months, as described by a number of participants. This inconsistency in determining more precisely the problematic times can also be seen in the literature with different time intervals reported. In some studies 7 days is regarded the maximum duration for adaptation to the appliance due to a reduction in the pain (Sergl *et al.*, 1998) while other studies quote 14 days as the time required to adapt to the appliance (Brown and Moerenhout, 1991). This may be due to the time period of the investigation and diversity of the sample as the second study involved three different age ranges in their research. Chen *et al.* (2010) studied the OHRQoL of patients at six different times before, during and after treatment using OHIP-14 which contains a few questions about eating related difficulties. They found that 51.35% of patients indicated it was “uncomfortable to eat any food” and 33.78% “had an unsatisfactory diet”. The first week after insertion of the appliance was the time when the greatest deterioration in OHRQoL was observed and this lasted until one month after appliance insertion in which QoL gradually became better and reached the pre-treatment level. After completion of treatment the OHRQoL significantly improved. Similar results were observed by Zhang *et al.* (2008) who examined OHRQoL in orthodontic patients over a 6 month period at 4 different times starting from pre-treatment, first week, first month and 6 months after insertion of the fixed orthodontic appliances using the CPQ for measurements. Oral symptoms (OS) and functional limitation (FL) were the components that deteriorated the most, particularly after the first week and the first month. In this study the result of the QoL deterioration was reported at a domain level rather than reporting individual items. Therefore it's not possible to determine the exact relationship of eating deterioration with time.

In the current study most patients also linked eating problems with pain at the start of the treatment. They also determined two different sources of pain at this time, one related to the pressure of the appliance on the dentition and the other due to the physical obstacle of the appliance itself. The first one appeared because of the continuous pressure of the appliance on the dentition which can be exacerbated during eating due to the acquired tenderness of the dentition. The second one happened mostly because of continuous rubbing of the peri-oral musculature and soft tissues with the appliance during eating and speaking. This pain can be regarded as secondary and was not reported by all of the participants. In a study of the attitude and perception of the patient towards orthodontic treatment, Lew (1993) also reported that 49% of patients felt discomfort in their cheeks and 63% of participants in their tongue. In addition to the increased intensity of pain, for some of the participants the physical obstacle of the appliance during the first day after insertion of the

appliance was reported to be one of the primary concerns during eating. This may be due to the unfamiliarity of the situation and inadaptability of the peri-oral musculature with the presence of the appliances during this time. To differentiate between these two sources of pain during the first days of the appliances further studies are necessary to obtain more in-depth information.

The time factor also includes the time that the participant needs for eating, which was highly likely to change during treatment. Because of the presence of the appliance in the mouth (particularly fixed appliances) and its physical intervention with the eating process either due to pain or due to the nature of the appliance which acted as a food retentive site. Generally, the patient needed longer to eat and they may observe that they were the last one who finished their meal. This happened due to the need to chew foods properly in order to make swallowing easier. Moreover, it was also related to sticking of the food particles and fibres to the appliances, requiring patients to remove the stuck foods using their tongue, lips, hand and in some conditions brushing which interrupts eating or makes the eating process last longer. Some participants indicated that they were the last person who finish the meal and sometimes, particularly when eating outside their home, they have to stop eating even though they are not completely full.

It was hard to find any differences in perception of functional eating difficulties in relation to time between the child and adult groups. This may be due to the effect of pain which appears in both age groups in the same biological way which is related to the initiation of pain during tooth movement. This was partly consistent with the finding of Brown and Moerenhout (1991) in which both pre-adolescents aged 11-13 and adults aged 18-30 years old had nearly the same amount of pain and showed similar psychological well-being over different stages of orthodontic treatment. Eating difficulties and pain seemed to follow a similar pattern for both age groups and eating deterioration was at its maximum level during the first week of treatment and reduced gradually after that. This may be due to adaptation to the treatment and gaining experience regarding how to face the difficulties (Carr *et al.*, 2001). These findings were inconsistent with those of Brown and Moerenhout (1991) who indicated that the adolescent groups aged 14-17 years old showed higher levels of pain and lower psychological well-being level compared to adults and pre-adolescents undergoing fixed orthodontic treatment. However other studies Zhang *et al.* (2008) and Liu *et al.* (2011) examining OHRQoL in children and adult orthodontic patients at different times during treatment indicated similar results across both age groups, more in line with the results of our study. Although these two studies used different OHRQoL measures, the results showed that for both children and adults OHRQoL deteriorated most at the start of the treatment and included functional difficulties.

Eating difficulties at the start of the treatment was a factor that caused some participants to express regret about commencing treatment or think about discontinuing their treatment. Inability to eat and its related pain was one of the obvious causes and this trend was mostly noticeable in the adult age group. Adults may experience more functional eating difficulties because of eating related psychological and emotional difficulties. Moreover the greater social activities of an adult's life in comparison with children may be another factor related to a higher rate of possible treatment discontinuity in relation to eating difficulties. An old study conducted by Haynes (1974) related discontinuation of treatment with psychological and emotional factors as they found that about 33.08 % of patients who were 15 years old and above discontinued the treatment while for the 10-14 year old patients the rates of discontinuity was 17.24%. In another study peer reaction was the initial fear of adult orthodontic patients and was expressed by 74%. However the authors suggested that adults with fixed orthodontic appliances can accept the new situation sooner and their negative concerns will not remain long (Tayer and Burek, 1981). The current study showed that the effect of eating difficulties early on in treatment did make some patients consider discontinuing their treatment. Bartsch *et al.* (1993) and Sergl *et al.* (1998) also indicated that the discomfort during the course of orthodontic treatment affected the compliance of the patients during treatment. Therefore, it is important to inform patients about all the possible difficulties including eating related problems and the fact that generally these are short term effects, because the lack of information about treatment related discomfort may be one of the main causes for early termination of the treatment. In order to understand the exact effect in this regard further studies are necessary to understand the effect of eating or pain initiated by eating in relation to the discontinuation of the treatment and how it is different between children and adult age groups.

One of the primary elements that can be resolved by time was the ability of patients to adapt to their new situation. All of the participants reported the difficulties of the eating related issues at the start of the treatment, while after a few days or one week they became familiar with the situation and coped with the appliance. The study of Mandall *et al.* (2006) on the effect of the fixed orthodontic appliances on daily life activity indicated that the impact of the fixed orthodontic appliance on eating was not reduced with time which is an indication of quick adaptation of patients to the appliance. The qualitative findings of the current study was relatively in contrast with this point. The qualitative findings explored that the impact of the time on the eating difficulties were high and different ERQoL deterioration can be seen at the start of the treatment. Likewise the impact of the treatment was continued throughout of the treatment for some of the eating difficulties and eating habit changes. Abed Al Jawad *et al.* (2012) found that patients did adapt to their orthodontic appliance once the initial pain had subsided

The other impact of time was the progression of treatment which demands activation of the appliance at different times. Activation is one of the vital steps in the process of orthodontic treatment. Different forms of adjustment and activation exist while the general principle of all is reapplication of a particular force on the teeth by the different components of the appliance. The current study highlighted the impact of appliance “activation” on eating difficulties and found that functional eating difficulties with different magnitude appear again after a period of remission which is mainly due to the pain (Figure 5.4). Moreover other dental intervention such as interproximal reduction, tooth extraction, adding some other components such as intraoral elastics, different anchorage devices also regarded as the causes of the eating difficulties. These difficulties were reported to be short and previous experience with eating difficulties helped them to deal with activation difficulties more quickly.

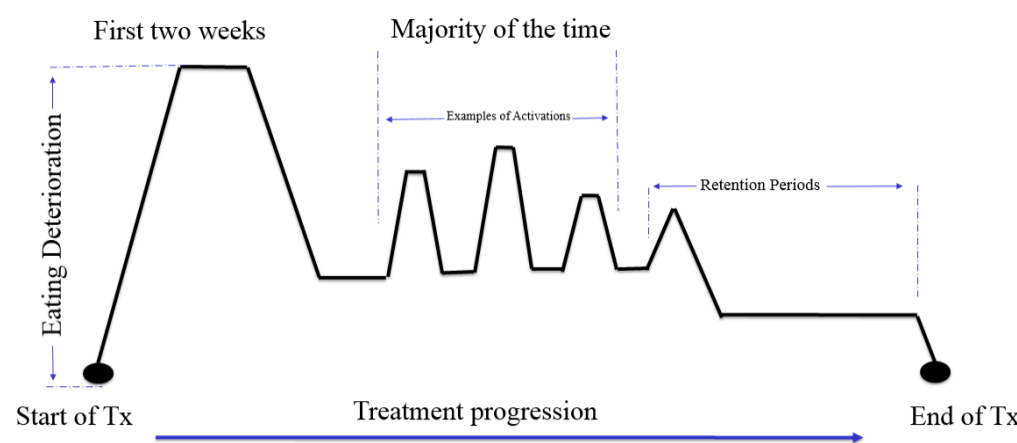


Figure 5.4 The impact of time and progression of the treatment

Prior to commencing treatment, expectation of eating difficulties was expressed by a small number of the participants. This may be due to the lack of awareness or information about the eating difficulties or QoL related problems in general by the patients and parents. Most of the patients who expected eating difficulties thought these would be generalised without realising the time of specific nature which becomes more obvious at the start of the treatment. Those who indicated their expectation for the eating difficulties had generally been made aware of these by other patients who have or have had orthodontic appliances. Whilst eating problems were predicted, the times of the likely difficulties were not identified or predicted clearly. Being able to predict

difficulties associated with a medical intervention may increase the compliance and psychological support as well as the satisfaction with the treatment outcome (Steinberg and Silverberg, 1986).

5.6.3.2 Social Impact during the Course of the Treatment

One of the other important factors that affected patients eating was the eating related social well-being which included both the location of the eating and the surrounding people. Home, workplace, school, university, relative's houses and restaurants were amongst the places repeatedly described by the participants. One of the most common findings was the feelings patients associated with eating outside the home and how they react in the presence of other people during eating. Needing a longer time to eat and the need to clean their teeth immediately after eating were regarded the most two important obstacles interfering with social interaction during the course of orthodontic treatment. However socializing during eating is one of the characteristics of human beings who like to share food and eat together in a family or wider social groups (Ochs and Shohet, 2006). Furthermore social facilitations is a phenomenon described by De Castro (1997) which shows that the presence of the other people during a meal time will influence the consumption of food and Hertrich and Hirschfelder (1990) indicated more consumption in social places than when alone in both normal and overweight persons. Later work by De Castro in 1990 described that a larger amount of food is eaten when other people are present during the meal time. This may simply be due to increased meal duration in the presence of others compared to when an individual eats alone (De Castro, 1990).

Family meals are still regarded as the main time for nutrient intake for family members, in particular young adults and adolescents and as a way of social interaction between them (Kerby, 2014). Eating at home and with family members was preferred by almost all the participants with orthodontic appliances. This may be related to the difficulties that the patient face when they eat outside or with other people. At home, they can choose the most suitable type of food for their appliance and can choose a suitable way of eating. Shifting to a soft diet at the start of the treatment and sometimes after activation of the appliance, having different ways of eating such as chopping hard foods to smaller particles and eating slowly were the most common reasons given for preferring to eat at home and with family members.

For children's groups, issues related to eating at school were discussed by only a few of the participants. These participants reported difficulties eating at school with their friends which may be due to the psychological impact of the appliance on eating where the children did not want to be embarrassed or given a negative picture on their eating with their schoolmates. The school system in Kurdistan differs from the UK in regards of the duration which the student remains at school, making it more feasible for a pupil to avoid eating in this environment. Generally, the

school time either starts at 8 am and finishes at 12:30, or starts 1:00 pm and finishes at 5:00 pm. This is due to a shortage of school places and aims to include as many pupils as possible in each school. This time has divided into 5 lessons with three 10 minutes rests between the lessons. During the rest time the children usually take snacks, which are mostly bought from the school shop. Some children reported being unable to eat at school with other children due to the time constraints and an inability to clean or brush their teeth. In the UK and other Westernized countries the school time is longer than in Kurdistan school and a school provided meal or packed lunch from home is regularly consumed on a daily basis. This may mean that UK children face more eating related difficulties at school due to the longer school time and because it is generally essential to eat at school.

Expression on the surrounding people's face or their emotion will also influence food choice and food preferences. If the surrounding people at the time of eating give a positive view or express pleasure during eating the desire to eat the disliked food would increase (Rousset *et al.*, 2008). This concept can be generalised for the adult group eating at their work places. Some of the adult orthodontic patients indicated selective food eating at their workplace to make the process of biting and chewing easier and reduce the chance of getting food stuck to their appliance. Furthermore, eating cautiously, feeling embarrassment and thinking about how other people may react will reduce food enjoyment and produce stress during eating. Stress is another psycho-physiological feature which influences dietary intake and food choices. It is not obvious whether stress reduces or increases food intake, therefore there is a contradictory relationship which is named by Stone and Brownell (1994) as "stress eating paradox". This paradox can be explained in two ways, the first one is a generic model, which hypothesised that stress produces food intake changes in general. "Individual differences" is the second model that predicts that only a particular group of the population are vulnerable to change their food intake due to the stress. Stress also may impose its effect on the type and quality of food selection and the amount of consumed food (Greeno and Wing, 1994).

Socialization in eating during the course of the treatment can be affected by peers and friends. Children are most likely to follow their siblings in food preference rather than their parents. The reasons behind such similarities in siblings are the similar age and fairly similar exposure to different foods (Birch, 1980; Pliner and Pelchat, 1986). Orthodontic treatment is mostly carried out during growth in adolescents and the effect of peer and sibling influences on the orthodontic patient have not yet been investigated. Whilst the similarities between the diets of children and their peers may be highly important, no rigorous studies are available, particularly in the dental and orthodontic literature. Some old studies have investigated this issue by exposing children to

those foods which are preferred by their peers, but which the children did not like themselves. As a result of this exposure, the children's preference reversed and shifted to their peer's model. Furthermore this preference lasted for several weeks after even in the absence of the initial social influences (Duncker, 1938; Marinho, 1942; Birch, 1980). Furthermore Farrow *et al.* (2011) found that friendship can affect eating and there were similarities in eating behaviour and attitude between participants and their best friends because peers can be regarded as a reference point for self-evaluation (Steinberg and Silverberg, 1986). In the current study, participants in both age groups indicated their preference to eat like others whilst sometimes it was challenging to eat the same food or in the same way as their friends. This experience made some of them avoid eating with their friends and reduce their socialization in eating because they cannot eat like them or eat the same food.

The other aspect of the social impact is related to the rejection of the offered food or invitation. Inability to eat every kind of offered food or fear of food particles sticking to their appliance were the main reasons given for rejecting food in social situations. This observation was mostly noticed with the adult groups which may be due to their increased social activities. Invitations to eat in a relative's house or eating all together in another place such as a restaurant or picnic is common practice amongst Kurdish families. Some of the participants were worried about such invitations and several factors were associated with this issue. One of the factors that caused the participant to reject an invitation or an offered food was the food type which the patient cannot bite, chew or swallow properly. This situation was worst during the first weeks after insertion when the patients had still not adapted to their appliances. An inability to clean the appliance and remove the stuck food particles and fibres either due to lack of available facilities for cleaning or feeling embarrassment can be regarded as the major points for such rejection. However, such reaction towards the offered food also happened at their own home due to the patient's intention to not re-brush the dentition and the brace immediately after eating. Therefore, most of the participants avoided having a dessert or fruits after the main course because they have already brushed their teeth earlier.

Support of family members at the start of treatment is also very important. It is essential for the orthodontist to inform patients not only of the eating related functional limitations, but also the social related eating issues during treatment particularly at the start of the treatment. It is well known that the instructions of the orthodontist are currently mostly related to functional problems, the need to preserve the appliance and maintenance of good oral hygiene measures (British Orthodontic Society, 2012). However, the patient should also understand the other perspective of the eating difficulties that may be produced by the treatment. The instruction should be delivered

in a language that the patient can understand easily and this advice should be directed first to the patients verbally by the orthodontist who is delivering the treatment. The clinician should also inform the parents about the forthcoming eating difficulties and how to help the children to eat properly without damaging the appliance and putting minimal pressure on the dentition that could result in pain. This will allow parents to provide better psychological support and greater assistance in proper food selection.

5.6.3.3 Food Selection and Limitation

a. Soft Food

Food limitation and selectively choosing foods that are easier to eat is another difficulty for the orthodontic patients during the course the treatment. This difficulty is also time dependent and can be seen mostly in the first month after inserting the appliances. The participants indicated that at the start of the treatment, they mainly limit themselves to foods which require less chewing and biting. The majority of the participants used the term *soft food* which refers to different kinds of foods with a soft or liquefied texture. Pain due to the orthodontic tooth movements at the start of the treatment and sometimes after the activation of the appliance was the most common cause for selecting the soft foods. Examples of the soft food includes different kind of soups, yogurts and juices. This finding is consistent with the findings of Abed Al Jawad *et al.* (2012) who described different kinds of softer foods to which the patients shifted during treatment to reduce pain sensation and make chewing more comfortable; however in this study the time when a softer diet was preferred was not clearly identified. One of the main soft foods described by the Kurdish orthodontic patients was called “*Shorba*” which consists of rice as the main ingredient. The water content and the cooking time can be increased to make this food softer and give a smooth and creamy texture. Most of the participants expressed their dislike for this food and some other kinds of soft food. The dislike of the “*Shorba*” may be due to a stereotype among the Kurdish population who generally prepare this food for sick individuals. This argument was also expressed by some the participants during the qualitative interviews.

“ At the start I had to just eat Shorba just like the sick people...” Sh 15 FF M, “I really don't like Shorba because I am not sick...” 12 FF CFG.

The other factor contributing to the dislike may be due to the texture of the these foods which are softer, however personal and social and cultural learned expectations about the particular food also play a role in such decision (Szczeniak, 2002). Having soft food was one of the factors that encouraged the orthodontic patients to eat at home, particularly at the start of the treatment. The main reason was due to the unavailability of such foods at school, university or work places. The

other reason was feeling shy or embarrassed eating such foods in front of their friends and surrounding people.

b. Hard food and chewy foods

The data indicated that hard and chewy foods were generally avoided, especially in the days after insertion of the appliances. Hard food and chewy foods were mentioned many times during the interviews and focus group discussions by each participant. The pain provocation by the hard and chewy food, particularly at the beginning of the treatment and after adjustments was reported by all of the participants. During this time the orthodontic patients with fixed orthodontic appliances are unable to bite and grind these foods. Whereas with removable appliance this difficulty was less or even absent because of its removal during eating. The amount of the force, the number of teeth being moved and removal of the appliance during eating may help to minimise pain at the start of the treatment. Although few patients with removable appliances participated in this study, our findings are similar to Sergl *et al.* (1998) who found that fixed orthodontic appliances produce a higher intensity of discomfort than both removable and functional appliances because of more adverse sensations in the periodontal ligament and its surrounding structures.

Hard and chewy foods were regarded as one of the important causes for bracket debonding during eating. The participants reported unfamiliarity with the appliances at the beginning of the treatment as the cause for the bracket debonding. The posterior brackets and bands were reported to be most vulnerable to debonding with chewy or hard food (section 5.5.6). Patients with a history of debonding during eating reported taking extra care to not repeat the situation and be more cautious when having such kind of foods. Moreover the participants indicated that questions about consumption of hard and chewy food were those most commonly expressed by the orthodontist after debonding, such as “*have you had hard or chewy food?*”.

c. Sticking of the Different Kinds of Foods with Orthodontic Appliances and its Impact on Eating

Sticking of the food debris and particles to the appliance was one of the problems that participants experienced during the course of the treatment, although it was considered a greater issue at the start of the treatment due to unfamiliarity with the appliance. This problem was noticed in both age groups and was greater in those patients who had a transpalatal arch, expansion devices such as a quad helix or Hyrax and intra oral elastics, because these act as an additional sites of food retention with fixed orthodontic appliances. This accumulation and adherence of different kind of foods to the orthodontic appliances imposes an effect on patients eating. According to the interview data, foods that are most liable to stick to the orthodontic appliance are:

1. Sticky food such as chocolate, chocolate bars and chewing gum
2. Strings (fibres) of different kinds of food such as chicken breast, and other type of meat, some kind of fruits such as oranges and watermelons. Some types of vegetable are mentioned although they are mostly concerned about it as a result of its colour that is more obvious and can be seen easily by other people.
3. Skins of some fruits such as apple and tomato.

Food stickiness with appliances was regarded one of the main reasons which interferes with social activities and plays a role in rejection of an offered food or invitation

When I am at work I always try to have a clean brace without any food being stuck to the brace. Because for some people this may be disgusting. At the office I have got brush and tooth paste after eating I go immediately and clean it. I try to finish my eating earlier so as to be able to clean before they finish.... if I don't have my brush I never eat outside... S 25 FF

All the participants reported being embarrassed in front of the other people when food becomes stuck to the appliance and that their main aim is how to remove these stuck particles. Some patients reported using their lip, tongue, or hand for removal or sometimes interrupted eating to brush their teeth during the meal time. This difficulty also caused some of the participants to put their hand in front of their mouth during speaking or even not speaking at all during the meal time. Of course, one of the ways people socialise is with interactive conversations during meal times when family or friends are around each other. One of the aspects of Kurdish culture which is still present is eating together as a family or visiting a relative's house for eating. Some orthodontic patients indicated the obvious impact of the food stickiness on meal time conversations. They thought about the judgments of the surrounding people and were afraid of giving a negative impression when they see foods stuck on the appliance. In the current study due to the diversity of the eating difficulties this aspect was not probed deeply and further qualitative studies may be required to uncover the other aspects of the stickiness of food with the orthodontic appliance and its impact on socialisation.

d. Drinks Limitation

Drinks limitation was described less by the participants due to the fact that drinking would not bring pain to the orthodontically moved teeth like hard and chewy foods. The primary concerns about the limitation of drinks were general knowledge about the hazards of some drinks to the dentition and to health in general. Furthermore, past experience of the dentist's instruction and current instruction of the orthodontist was another cause for the limitation. The most common

drinks reported to be avoided were fizzy and sugary drinks, due their irreversible effect on the teeth. Similarly, tea and coffee and coloured juice were also avoided due to discoloration of the dentition and the appliances.

Therefore, some participants completely avoided those drinks even though they would have liked to have them. They believed that with the presence of the brackets it is impossible to clean and remove the stain that was formed by coloured drinks. Fernandes *et al.* (2012) also found that tea and coffee were the most coloured drinks, which cause discoloration of the transparent elastic ligatures. Furthermore, recently Talic and Almudhi (2016) found the same result and reported that tea and coffee are most likely to cause discoloration.

The type of appliance and brackets used, also influenced drinks consumed. For example, those who had transparent retainers and white ceramic brackets avoided coloured drinks such as tea, coffee, coloured fizzy drinks and juices. This is to preserve the appliance or the bracket from the discolorations. Rinsing the mouth with plain water directly after drinking was described by some of the interviewees as a precaution to wash away the rest of the coloured drinks from the appliance and dentition and reduce its effect. The stage of the treatment, was another factor influencing drink selection or limitation. For instance, those who were using intra oral elastics, transparent power chain and ligature elastics reported avoiding coloured and very hot drinks. The reason behind this was orthodontists instruction to keep the colours and the force of the elastics as optimally as possible and reduce the discolouration. Oshagh *et al.* (2015) compared three different means of space closure and found that the temperature of drinks such as tea would decrease the force of the elastic chains by half after 3 intakes of 1.5 litres of tea boiled at 65°C.

The finding that hot and cold drink were also avoided by other patients may be related to a particular stage of the treatment for e.g. after interproximal enamel reduction, which may lead to dentinal hypersensitivity. However, Zachrisson *et al.* (2011) indicated no increased dental sensitivity to a temperature change. The use of topical fluoride application and fluoridated mouth rinses and toothpastes may be the cause of such inconsistency.

5.6.3.4 Positive and Negative Perceptions about Food Selection and Limitation

Most of the participants expressed negative perceptions towards the soft diet at the start of the treatment due to the texture and the taste of such foods, while some others regarded selectively choosing such food as a healthier way of eating. This finding was also consistent with the other two previous qualitative studies on the impact of orthodontic appliances on eating (Abed Al Jawad *et al.*, 2012; Carter *et al.*, 2015). Eating slowly and having smaller mouthfuls was reported to make the swallowing process easier which leads to exposure of a larger surface area of the food particles to the salivary enzymatic activity in the mouth (Ngom *et al.*, 2007; Magalhaes *et al.*, 2010).

Additionally, some of the participants in both age groups described the treatment as an adjunctive for losing body weight due to the decrease in the amount of food eaten and low speed of eating which sometimes makes them finish their meal before getting full. This was mostly described by those patients who were already overweight or were on a diet. On the other hand, some others described the food limitation negatively and related it to unwanted weight loss particularly for those who were already thin. Furthermore, avoiding their favourite foods which cannot be eaten due to the pain, biting and chewing difficulties, stickiness with appliance and teeth and the cleaning demands was also regarded as a negative aspect of food selection and limitation.

To sum up, it is obvious that everyone has his/her style of eating and always follows that pattern. This pattern will change according to the culture and tradition of the person or his /her nation in a wider extent. In addition, the eating habit may change according to the personality, types of food, medical status and sometimes on the venue of the eating. Orthodontic treatment is mostly carried out in the adolescence period which is regarded as an important time for growth and development. Any change during this time may produce its influences in adulthood and any deterioration in this period may impose its impact on long term health and well-being. Adult patients also face the eating habit changes during treatment but its long term effects and consequences are more likely to stop at the end of the treatment.

5.6.3.5 Changing Eating Habits during Orthodontic Treatment

Participants reported changes in eating habits during orthodontic treatment. These changes were variable and depended on personal and social factors as well as the time within treatment. For example, chopping foods into smaller pieces and eating less were mostly reported during the early days shortly after starting treatment.

a. Type of Food

Eating habit changes are likely to affect eating enjoyment and push orthodontic patients to follow an acquired style of eating, which may not be preferred by all patients. As discussed earlier pain is the main factor that causes patients to adopt different eating habits, which are likely to change from the beginning of the treatment. Shifting to a soft diet can be regarded as the first habit change to reduce the pain that will be aggravated by harder and chewier foods. These foods may have been consumed daily prior to application of the appliance, but because they require greater biting and chewing demands, which exert more pressure on the dentition, patients either shift to a softer diet or at least use mostly their back teeth, which are not engaged with the appliance. This trend was mostly reported in the adult groups rather than the child aged patients. This is may be due to the presence of a full adult dentition including first and second molars. Therefore, in fixed

appliance cases which often end at the first molars, patients have one or two teeth in each quadrant which are not involved in the tooth movement. Additionally, the first molar is a large multi-rooted tooth and the amount of the force delivered by flexible aligning wires will not be as great as the force exerted on a single-rooted tooth. This information may be useful to inform patients during the instruction time as patients may find it easier to eat with these teeth during the earlier stages of treatment. The molar teeth may need more force to be moved (Proffit, 2007) and the amount of the force will be distributed on the larger root surfaces compared to anterior teeth (Hixon *et al.*, 1969; Quinn and Yoshikawa, 1985). Therefore the amount of force on the molars will be distributed on the larger surface area and intensity of the pain may be lesser than the anterior teeth. However the molar teeth face another problem which relates to the elastic separator insertion prior to molar band placement. Some participants in the qualitative study reported intense pain one day after the insertion of separators which affected eating.

b. Eating Speed

Reducing the speed of eating was another perceived eating habit change during treatment. Pain and the physical obstacle of the appliance itself were found to be the major causes of introducing a slower eating habit. The most common issue described by the participant as a result of the reduced eating speed was being the last person who finishes their meal. Sometimes this forced participants to give up eating without feeling full. Being highly cautious during eating due to thinking about surrounding peoples' judgments and not wanting to give a negative impression also contributed to a slower eating habit. This is may be one of the causes of weight loss at the beginning of the treatment which may be due to not finishing meals resulting in a lower energy intake. Sticking of the food to the appliance was regarded as another cause for the slowness in eating. The time required to remove the stuck food either during eating with tongue, lips and hand or immediate brushing after eating were the most common reasons for being unable to complete their meal.

On the other hand, some of the participants described the reduced eating speed as a positive acquired habit and wished to continue in the same manner after the treatment. They linked a slower eating habit with a healthy way of eating in which the mouthful is retained for a longer time allowing more chewing and easier swallowing. This will increase the chance of enzymatic salivary actions by exposing the food to more saliva (English *et al.*, 2002; Ngom *et al.*, 2007; Magalhaes *et al.*, 2010).

c. Cutting the Food into Smaller Pieces

Another reported habit was cutting up the foods into smaller pieces, especially the hard foods like apple, carrots, and different types of breads to make the chewing process easier and less uncomfortable. A similar habit has been reported by denture wearers: Kelly *et al.* (2012) asked two questions about the impact of dentures on whether patients chopped or sliced their food to make the eating process easier. This habit was also linked with the instruction of the orthodontist to preserve the appliance from debonding and breakage. These findings are consistent with the study of Johal *et al.* (2013) who found that nearly half of the patients chopped their food into smaller pieces and 79.3% of the orthodontic patients were influenced by the advice of their orthodontist to avoid hard and sticky foods. In this qualitative study patients reported cutting up some of the foods into smaller pieces because the orthodontist emphasised this as a way to preserve their appliance.

d. The Amount of Food Eaten

The data indicated that amount of food eaten was also affected during the treatment time particularly at the start of the treatment. Different factors including pain, slowness in eating, the physical obstacle of the appliance and some other eating habit changes forced patients to consume less food compared to the pre-insertion time. This was also viewed positively as a healthier eating habit by some of the adult participants while others regarded it as having a negative effect on their body shape. This view was mostly expressed by those participants who were already thin and felt the orthodontic treatment was the main cause for weight change and looking skinnier. However for some patients this change was temporary and limited to the start or a few months after insertion of the appliance. The issue of weight change and its relation with the change in the amount of eating foods due to the orthodontic appliance was probed deeply. This is in contrast to the Carter *et al.* (2015) qualitative study in which the weight change in relation to the appliances not mentioned clearly. Johal *et al.* (2013) found changes in BMI and fat percentage during orthodontic treatment, particularly in overweight patients and used this change as a predictor for the dietary behaviour. In the present study weight change was recognised as one of the obvious sub-themes and by probing the impact of the appliance on the weight change may uncover another aspect of eating difficulties during orthodontic treatment (Johal *et al.*, 2013).

5.7 Strengths and Limitations of the Study

Conducting qualitative studies with a non- English speaking population is regarded as one of the main difficulties for an English researcher (Lopez *et al.*, 2008). The main qualitative study was performed in the Kurdish language which is the researcher's first language. This allowed the process of data collection to be conducted fluently and the emergent themes to be probed more confidently. Furthermore the participants could communicate with the researcher freely without a

language barrier. Hatton (1992) indicated the difficulties in undertaking qualitative research in a health care setting when language differences exist between the health provider and the patients even if a translator was present during the session. This is mostly because translation from the source language to a second language cannot transmit all the cultural and individual identities because languages are very different. Grossman (2010) reported that the translator must “develop a keen sense of style in both languages, honing and expanding our critical awareness of the emotional impact of words, the social aura that surrounds them, the setting and mood that informs them, the atmosphere they create”. Therefore the translation should contain the contextual meaning rather than simple translation of words which may result in missing some words where a comparable translation cannot be found in the source language (Twinn, 1997).

Nvivo is a program designed to organise the analysis of the qualitative data. However, due to incompatibility of the Kurdish alphabets this program was not used. Microsoft Word was successfully used for the framework analysis / charting to organise the data (appendix F).

The focus group discussions were found to be difficult particularly with the child groups. Most of the time the discussion was between the researcher and individual participants rather than spontaneous discussion between the children. This partly may be due to the inexperience of the researcher in moderating focus groups. Therefore the data from the focus group was not felt to be as informative as the qualitative interviews. However the focus group confirmed the findings of the interviews and most of the data from both approaches yielded similar information.

5.8 Summary

This study is the first to have used qualitative research to explore orthodontic related eating difficulties in a sample of Kurdish adolescents and young adults. Eating is one of the common problems that face patients during the course of orthodontic treatment. In order to find the perception of patients on ERQoL during the treatment a qualitative study performed with two age groups of orthodontic patients, children (11-16 years old) and adults (17-25 years old). After the framework analysis of the semi-structured interviews and focus groups several factors were identified in relation to the deterioration of ERQoL during the treatment time. The first factor was time, in which at the start of the treatment most of the functional difficulties arise in both of the groups such as biting, chewing and sometimes swallowing difficulties. Pain in the dentition was regarded as the most likely cause for such functional limitation, which mostly appeared at the start of the treatment and sometimes after activations of the appliance but with lesser magnitude than the period after insertion of the appliances. Social related factors were also another issue that affected ERQoL and most of the major differences between the two groups were found here, mostly related to the social activity which is mainly influenced by the surrounding people and the

venue of eating. Functional and social related factors affected food selection and limitation and the change in eating habits. Most of the patients in both groups used soft diet and avoided hard, chewy and sticky foods especially at the beginning of the treatment. Reducing eating speed, cautious eating to avoid food getting stuck in the appliance and preserve the appliances were the common eating habit changes seen in both age groups.

6 Chapter Six: General Discussion

6.1 Introduction

This research project provides examples of how qualitative and mixed methods research can be successfully deployed in the field of orthodontic research, adding to the growing body of qualitative evidence within the discipline, first by generating new qualitative data on ERQoL and second by using a mixed methods approach to develop a questionnaire.

In this research two qualitative studies were utilised to inform ERQoL following orthodontic treatment (Figure 6.1). Data from Carter *et al.* (2015) were used to 1) underpin the development of a topic guide for a qualitative study in a different culture (Kurdistan) and 2) to underpin the development of a mixed methods ERQoL questionnaire for a UK child audience. The Kurdistan qualitative study was conducted with two age groups of orthodontic patients to expand the knowledge about the eating difficulties during orthodontic treatment and explore possible age and cultural differences with this treatment (between UK and Kurdistan). In the questionnaire development study both qualitative and quantitative methods were used to develop an instrument that can be used in the future to collect data from a larger sample size.

6.2 The Relationship Between the Two Studies

The topic guide for the Kurdistan interviews included all issues raised in the previous study by (Carter *et al.*, 2015) which was based on a UK population. Therefore part of the work was to explore if cultural and or age specific factors existed that were different to those identified in the UK study (Carter *et al.*, 2015). The focus group topic guide was derived primarily from findings of the qualitative interviews that were conducted in Kurdistan (appendix E2). The interviews were conducted ahead of the focus groups primarily because recruitment to the focus groups proved very challenging, as most of the approached participant found focus group attendance to be difficult and nearly half of them refused to participate in the first place (Table 5.1). However, this approach did allow the topic guide for the focus groups to be constructed in a culturally appropriate context and some participants were still keen to contribute in the study, and so they were participated in the face to face interview.

It was planned to conduct the Kurdistan qualitative study after complete development of the ERQoL questionnaire. However, due to considerable time challenges related to obtaining the necessary ethical approvals for the questionnaire study, after completing initial draft of the questionnaire stage the researcher returned back to Kurdistan-Iraq to start the qualitative part of the study. However this unexpected event identified some advantages which strengthened the bond between the two studies. After finishing the qualitative data collection in Kurdistan the researcher returned back to the UK to complete the remaining face validity and reliability stages parts of the

questionnaire development study. With the reliability stage some questions were identified to be deleted in the questionnaire but with the additional insight from the findings of the Kurdistan qualitative study and the UK face validity interviews these questions were found to be highly relevant to and important to be maintained in the developed questionnaire (see section 4.5.4). Therefore, these questions were retained in the questionnaire and the linkage between the two studies further reinforced. This also indicated the importance of using qualitative findings during the questionnaire development to make the measure reflect patients experiences and perceptions as closely possible.

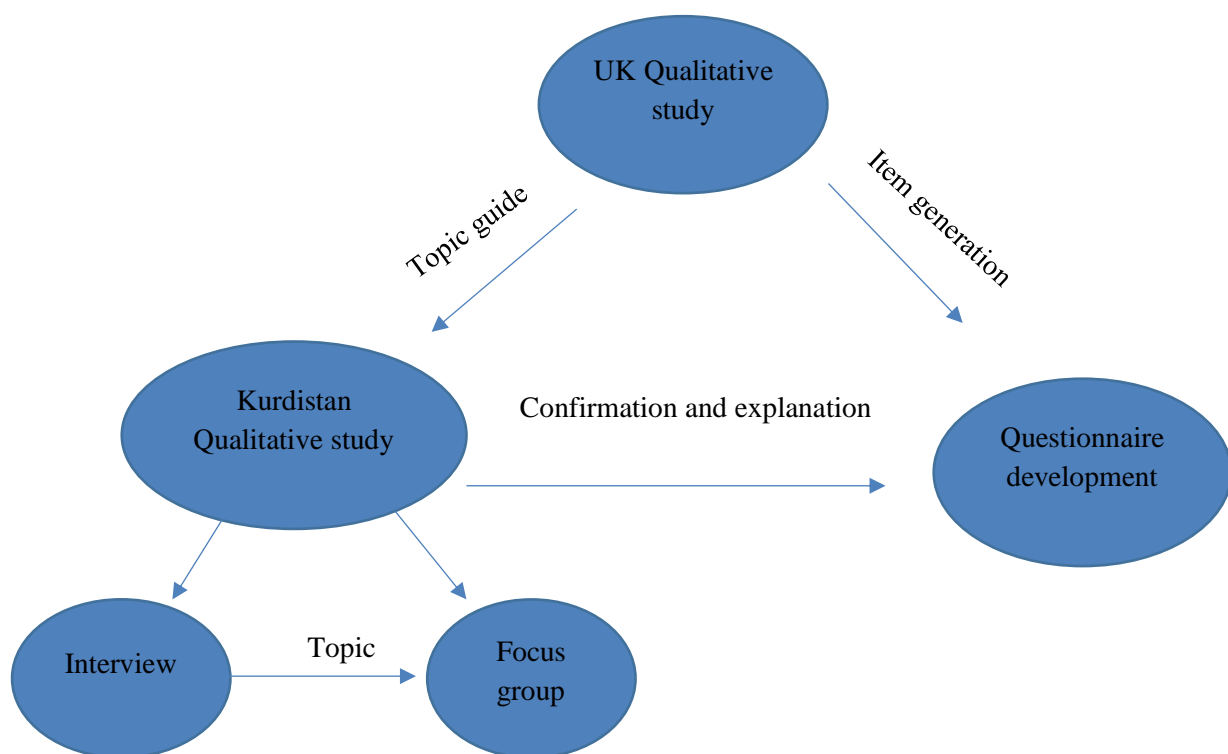


Figure 6.1 Relationships between the studies.

The age of the participants who participated in the Kurdistan qualitative study was divided into two age groups, children (11-16 years old) and adults (17-25 years old). These age ranges included the majority of the age range who seek orthodontic treatment. Carter *et al.* (2015) recruited 11-14 years old in their qualitative study. However, 15 and 16 year old orthodontic patients are quite common and still they are undergoing growth and development. Data from previous studies and particularly the CPQ 11-14 instrument may have influenced the selection of 11-14 year old children in previous studies. Therefore, in the Kurdistan qualitative study the children age group

was 11-16 years old to include this important age group and explore their perception about eating related difficulties, whilst also facilitating the recruitment process. Nevertheless, the UK and Kurdistan children group findings were very close to each other and very similar themes detected. This allowed us to involve the Kurdistan qualitative study findings to help confirm and explain issues raised in the developed questionnaire.

Therefore, the Kurdistan qualitative study added more detailed information about ERQoL which was used to expand our knowledge around eating difficulties. This served to inform any commonality between the data which could be used to inform modified versions of the ERQoL questionnaire to apply to different age groups and cultures in the future. The data from the child sample in Kurdistan were useful for justifying retention of those questions which were proposed to be deleted in the testing procedure particularly test re-test reliability.

6.3 Age and Cultural Differences in ERQoL during Orthodontic Treatment

The current study was performed in two different locations, the UK and Kurdistan-Iraq and therefore enabled evaluation of ERQoL in both cultures and both child (UK and Kurdistan) and adult (Kurdistan only) groups.

One of the important findings of this study was that the eating related difficulties are common across both cultures and age groups and the start of the treatment was the time of highest level of difficulties which may cause functional and social limitations for both cultures and both age groups. Therefore it can be stated that the time dependant factor is generalizable with all orthodontic patients regardless of their age and location. Functional difficulties were also regarded as a universal problem with orthodontic treatment and the results in of both studies (questionnaire development and qualitative work) highlighted this issue. Biting, chewing, and sometimes swallowing difficulties were common functional difficulties to both cultures and ages and pain regarded as the main cause for such difficulties. In both culture and age groups different type of hard and chewy food avoided to overcome these difficulties. Additionally a soft diet was consumed mostly at the start of the treatment and sometimes after activations. Therefore a translated version of the ERQoL questionnaire without modification can be used with Kurdish children (11-16 years old) after validation of the translation from a sample of orthodontic patients. Differences in food selection may be related to individual and cultural preference rather than the true effect of the orthodontic appliances. For example some Kurdish participants selected soft diet like *Muhalabi* and *Shorba* while in the UK the some of the children tried to have *pasta* and *yogurt* which are also soft foods. However most of the participants in both locations and both age groups indicated difficulties eating different kinds of meats, apple, carrot, chocolate and toffees. They introduced new habits by reducing their eating speed and chopping them in to smaller pieces to make grinding

and swallowing easier. As such, it can be claimed that functional difficulties are common to all groups and that differences are influenced primarily by cultural and individual preferences. However in the Kurdish population the participants identified one another reason for such limitation which was preservation of the appliance from breakage and debonding and such argument cannot be seen as clearly in the UK qualitative data. This may be due to the way of instruction by the orthodontists in Kurdistan who may have placed more emphasis on the preservation of the appliance as indicated by the participants (section 5.5.7.3). Alternatively it may be because the older participants in Kurdistan take a greater responsibility for their appliances, or because the UK National Health system does not impose a financial penalty for breakages therefore making breakages only an inconvenience in terms of time. In the current questionnaire the Q24 in the fifth domain *you and your dentist (orthodontist)* is asking general question about the influence of the orthodontist to change the eating foods without identifying the idea of the preservation of the appliance. As such in the application of the ERQoL questionnaire this issue could be taken in consideration and the question reformulated to highlight the importance of orthodontists advice in preserving the appliance during eating.

Social problems with eating during orthodontic treatment were identified as a common variables across studies. Social factors also interacted with the venue of eating in both cultures which produces its influences on the psycho-emotional attitude of the patients and affects eating enjoyment in both cultures and both age groups. However, generally speaking, the results indicated that adults were more affected probably due to more social activities and the demands of the daily job. Although gender difference was not a focus of this study socially related issues were mostly seen in female orthodontic patients particularly in Kurdistan and further studies may be required to investigate this. This may be due to females being more concerned about their appearance, having greater sensitivity and being more critical about their dental aesthetics (Hassel *et al.*, 2008; Tin-Oo *et al.*, 2011). Female participants appeared to be more aware of their eating particularly outside home and with other people to not give a negative impression by having food remnants stuck with the appliance. In both cultures, age groups and both genders social limitations exist but they are also dependant on the individual. However to strengthen these observations a further study on the eating related social limitations could be conducted in both age groups and genders separately.

Due to the daily school time difference in the UK and Kurdistan, UK children were found to be more concerned about eating at school because they eat in larger groups and generally have lunch and sometimes breakfast with their school friends. In contrast, in Kurdistan the majority of children do not eat at school. However some children may snack during the break time between the lessons

but this is more likely to be avoided by the orthodontic patients. During application of the questionnaire in Kurdistan this issue should be taken in consideration. Although the questionnaire includes a question (Q17) related to eating difficulty at school this is included as an example of a question that asks more broadly about eating difficulties outside the home. Therefore this question still can be used for Kurdish children without any change, but the results should be interpreted with caution.

Clinically, the orthodontist should pay more attention to such difficulties and inform the patients that difficulties are generally temporary and mostly limited to the beginning of the treatment. The current research has indicated that most of the difficulties are temporary and after adaptation to treatment almost all the ERQoL would return back to closer to the normal situation. Chen *et al.* (2010) also reported that one month after insertion of the appliance the number of complaints from the patient reduced and OHRQoL reached the pre-treatment level. This tendency to adapt to the treatment can be seen clearly in both UK and Kurdistan qualitative study and free text area answers of the developed questionnaire (see sections 4.4.15 and 5.5.4). Comparing functional difficulties with pre-treatment level may give an indication of ERQoL deterioration during treatment, because oral symptoms or functional limitations are rare in patients with malocclusion (Feu *et al.*, 2010; Marshman *et al.*, 2010) thereby allowing patients to easily detect changes in ERQoL after starting treatment. Therefore, when determining the ERQoL deterioration of orthodontic patients during the treatment, it may be better to compare with patients who are about to finish treatment and have had a maximum time of adaptation. Patients are also more likely to be psycho-emotionally stable because the stress of the treatment is about to end and the goal of the treatment which is the correction of the malaligned teeth is nearly completed. The findings of this research therefore suggest that if clinicians are comparing the impact of the treatment on the patients ERQoL then the comparisons should be performed with patients situations at the end of treatment. Therefore it is more practical to use the current ERQoL questionnaire in different culture and nations to reach an absolute conclusion about the universality of ERQoL matters of the orthodontic treatment

6.4 Food and Drink Selection and Limitation

This research has identified that patients experience difficulties of eating both hard and chewy foods. Additionally, the orthodontist will provide advice to avoid such foods with the aim of preserving the appliances.

The reasons for avoiding the hard and chewy foods can be summarised as below:

1. Due to pain (at the start of the treatment mostly)

2. Preserving the appliance because they regarded hard and chewy foods as a primary element for bracket debonding.
3. Orthodontists instructions (with a view to preserving the appliance)

However the findings showed that rather than total avoidance some patients devised coping strategies or changed food preparation to enable the consumption of such foods. Such knowledge can inform what is recommended to patients in clinical practice, for example:

- a. Chopping foods to smaller pieces (whilst being cautious with children due to choking risk)
- b. Using the most posterior teeth that are not affected by or included in the appliance. (i.e. maxillary and mandibular second and third molars).
- c. Using a juicer to prepare foods in way that is acceptable to patients but avoids the need to bite and chew (e.g. apple, pomegranate, and carrot).
- d. Avoiding advice regarding the consumption of softer foods that are not acceptable to patients (e.g. Shorba)

In the present research the foods that were found to be commonly avoided were different kinds of hard, chewy and sticky foods such as meat (particularly chicken breast), some kinds of breads, apple, carrot, nuts, chewing gum and chocolate bars and drinks like fizzy drinks, tea and coffee in the Kurdish population. In the UK also these foods and drinks were also mentioned by most of the participants (Table 4.22). Interestingly, previously published data have also identified these types of foods as being problematical (Abed Al Jawad *et al.*, 2012; Carter *et al.*, 2015). Moreover, the “*Teeth and Brace Friendly Food and Drinks*” patient information leaflet by the British Orthodontic Society (British Orthodontic Society, 2012), mentioned avoiding hard, crunchy and sticky foods such as apple, carrot, biscuit, nuts, chicken wing, toffee, caramel, fizzy and soft drinks. The present data on food avoidance is therefore consistent with most of this advice and previous findings. This may lead to a conclusion that although there are a wide range of cultural differences, food avoidance during orthodontic treatment may be universal and the patients will face the same ERQoL difficulties throughout the course of the treatment.

Social limitation was one of the important findings of this study which is highly interlinked with functional limitations of orthodontic treatment. In both the UK and Kurdistan qualitative studies these issues can be clearly seen while, the British Orthodontic Society instruction leaflet (British Orthodontic Society, 2012) does not mention this issue at all. The instruction leaflet is mostly directed to preserve the appliance and dentition without considering the psycho-social aspects of

patients undergoing orthodontic treatment. It may be more helpful to highlight the largely temporary nature of the food limitations, avoidance and difficulties. Furthermore focusing on the adaptation to treatment after insertion of the appliance may help better preparation for the treatment conditions. Therefore the next version of the “*Teeth and Brace Friendly Food and Drink*” patient information leaflet by (British Orthodontic Society, 2012) could be modified to include more ERQoL aspects of the orthodontic treatment.

6.5 Clinical Implications of the Research Findings

6.5.1 How to Deliver Dietary Instructions to Orthodontic Patients

Instructions have an important role in the orthodontic treatment. The instructions will clarify the vision of the patients and guide them to the proper action or reaction during the course of treatment because a scientific instruction provide positive impact on the preparation of the patients for the steps of the treatment (Lindsay and Jackson, 1993). Orthodontic treatment is a lengthy procedure and time dependent therapy and it is crucial to inform the patients the chronological difficulties that might happen throughout the treatment. Therefore it is important for the orthodontist to emphasise on the issue of adaptation to the eating difficulties which is appear between the first and second week after insertion of the appliances. This issue was clearly identified in Kurdistan qualitative study and the participants during the face validity stage of the developed questionnaire indicated the relevancy of this issue (Witt and Bartsch, 1996). There are many ways for delivering the instructions to the patients such as instructions given directly and verbally by the orthodontist, assistants or other staff. Furthermore, ensuring there is dedicated time for instructions will aid in the delivery and acceptance of the instructions by the patients. The type of the instructions may vary according to the type of the treatments, its progression, age of the patient and the severity of the condition. The core of this discussion can be extracted from the qualitative data of the current study and from the information about the ERQoL expressed by the patients during the development of the questionnaire. In addition to that the specific information about the way of delivering the dietary instruction probed with participants during the interviews and focus groups. The objective of this probing was to have information about the preferred method of instruction delivery from the patients view and implementing those views in a prototype of the dietary instruction. Likewise in the developed questionnaire also a separate domain specified to the relation of the patient, orthodontist and the instructions. The aim of these questions was to collect more information from a larger sample about the usefulness and practicality of the orthodontists instructions and advice.

Orthodontic treatment requires continuous instruction and support throughout the course of treatment while most of these instructions are locally and spontaneously given by the orthodontist according to the previous experiences. Activation of the appliance is a continuous procedure and

according to both qualitative studies, sometimes the activation would bring back some eating difficulties and patients should be made aware of this. Study participants referred to these procedures as *tightening* and in Kurdistan as *توننکردنموه* which has exactly the meaning. Therefore in the developed questionnaire a question about the effect of tightening the appliances used the word '*tightening*' instead of activation to make the question as near to patients' real perception as possible which would increase the rate of understanding and comprehension by the child orthodontic patients (Witt and Bartsch, 1996). This is also would make the application of the questionnaire in Kurdistan easier due to the similarities in perceptions and even in the expressions.

6.5.2 Essential Information to be included in Dietary Instructions for Orthodontic Patients

Orthodontists will routinely provide instruction to orthodontic patients after insertion of their appliance. Often, these instructions are general and some of the participants indicated that the core of the instructions are related to oral hygiene and preservation of the appliances. It is true that these essences are somehow linked to the eating, but eating and eating difficulties are not generally given priority in the instructions. Therefore, we can say that eating instruction is likely to be third place after the oral hygiene and preservation instruction in orthodontist's viewpoints. This prioritisation may be transmitted to the patients unknowingly and either positively or negatively affect their eating and therefore daily dietary intake. Therefore, the orthodontist should be able to send a message about the importance of dietary instruction in a way that could help regulate the intention of the patient to face the difficulties, because humans will do what they intend (Gollwitzer, 1999).

According to the analysis of the qualitative data eating is regarded as a primary cause that demands cleaning and is the most obvious cause for bracket debonding and appliance breakage. As such, it is fundamental to change the priority perception in the instruction and be more open about dietary instruction and respect it as one of the central points in the process of the instruction.

Dietary instructions can be classified according to five factors which in turn each of them has an unambiguous impact on ERQoL of the patients. The five factors are time, types of food, severity of the condition, types of the appliances and psychosocial aspects. If all of these subjects are integrated, a scientific instruction can be established in which eating and eating difficulties may be considered an important component of orthodontic instructions, which can be delivered at any time before or during the treatment.

6.5.3 How to Cope with Eating Difficulties

To help cope with eating difficulties the patients should receive organised and scientific instructions. First of all, it is important to inform the patient that they can eat most of the foods that they had before the brace, but some foods and drinks are more susceptible to be difficult and

need special attention. However, whilst some foods may be found to be more difficult to eat, the difficulties are temporary in most of cases and limited to or worst at the start of the treatment. Moreover, changing the style of eating, ways of preparation and careful eating will mean that some of these difficult foods can still be eaten. In this study the patient's experiences are used to provide the backbone for the instructions and this was one the aims of the study to capture the patient's perception qualitatively and using it to derive a prototype for dietary instruction during orthodontic treatment. According to the analysis and interpretation of the qualitative data and the answers of the developed questionnaire, the instructions should contain these points to guide the patients how to face the eating difficulties and how to manage the dietary intake.

1. Soft diet is the most common and easiest step when patients feel difficulties in eating some of the normal daily foods, particularly at the start of the treatment and after some of the activations. Different kinds of soups and broths or using it to soften other kinds of foods like bread, meats and vegetables can be useful during this stage. Some patients may be not happy with this and it is important to insist on the temporariness of consuming a soft diet. Furthermore, some of the hard or semi-hard fruit can be eaten by using a juicer or blender to have the nutritional benefit of these foods and but making them easier to eat. Changing the cooking conditions of some food like rice and meat would make the food softer and meaning it can be chewed and swallowed without difficulties. If the patients find eating normal foods at school, university or their workplace are difficult at this time, they may be able to have their own softer diet.
2. Changes in eating habit varies from one person to another, however changing the eating habit can be used as one the strategies to confront eating problems during treatment. Examples of changes in eating habits that patients found helpful are:
 - Cutting some foods into smaller pieces to make chewing and swallowing easier and minimizing the need for biting.
 - Slowing down the speed of eating, which helps them to eat comfortably and to grind and swallow the mouthful properly. With this habit also they may also reduce the incidence of bracket debonding and brace breakage. Interestingly, some of the orthodontic patient felt this to be a healthier style of eating.
 - Retaining the food in the mouth for longer periods to chew it properly, which makes swallowing and digestion easier.
3. Getting food stuck in the appliance is normal and this will happen to everyone with a brace. If food gets stuck in the appliance the patients can carry on eating and when finished they can clean it thoroughly. If they find this is embarrassing, particularly outside home, it is helpful to

not eat sticky foods like chocolate bars, biscuits, some sweets and stringy foods like chicken breast or they can use their tongue and lips to remove the stuck food with help of drinking water.

4. They may find eating in front other people to be difficult particularly at the start of the treatment. It may be helpful to lessen the meals in the public places, particularly during the 1st two weeks and after some of the activations if the pain started to appear again. This allows them to take their time for eating and finish the meal without increasing concerns and thinking about the surrounding peoples' judgments. This point may not be practical for all patients but at least it is important to warn them that they may find eating can be difficult in some situations. If there are no other choices and they have to eat in front of others in a public place like school, university or workplace, it may be helpful to take their own meals as well as their brush and toothpaste. If brushing facilities are not accessible it may be helpful just to rinse the mouth several times with plain water.
5. The patients may lose body weight due to a sudden reduction in the amount of food eaten. This mostly limited to the 1st month of the treatment and when they have learnt how to cope with the appliance and the pain has reduced they are likely to return back to eating the same amount of food as before. Therefore, they will probably return to their normal weight. By increasing the time of eating with cautious eating and reducing the eating speed, consuming a softer diet and cutting the foods to smaller pieces they may overcome this problem and they can generally eat most of the foods that they like. Orthodontists should be aware of this point particularly for those patients who are normal or underweight to instruct them to avoid reducing the food intake and insist on having a normal amount of food intake. However, some people who are overweight found this point to be positive because they reduced the amount of food eaten and snacking which helped them to reduce their body weight. On the other hand it is important to inform them that the reduction should be in-keeping with a healthy diet. Moreover, reducing chocolate, fizzy and sugary drink consumption and providing more time for chewing due to the slowness in eating was also regarded as a healthier style of eating by some of the orthodontic patients.
6. With some removable appliances and retainers eating should not be very difficult because patients can remove the appliance at the time of eating. The main difficulties of these appliances are continuous removal and insertion for eating.
7. Impacted tooth exposure and maxillary expansion with different kinds of expander can be referred as complex conditions which could have more impact on eating. It may be useful to advise patients that they may face more difficulties than other patients. Being careful during

eating, slower eating, smaller morsel and drinking water intermittently at the time of eating may reduce some of the problems.

8. Brushing is one of the big and important tasks during orthodontic treatment, which is important because it makes oral condition healthier and helps keep the teeth and periodontal tissues sound and free of disease. Sometimes the patients do not want to have a snack or even a meal because of the necessity of brushing and cleaning. It is not always necessary to have a proper brush after every food intake, sometimes the patients can postpone the brushing for a few hours (depending on what has been eaten), but at least they should rinse their mouth with mouthwash or plain water. This would help keep the brace and teeth clean and they can still enjoy your eating. It is important for the orthodontists to inform the patients that brushing should not be regarded as an obstacle to eating. Brushing is one of the normal daily activities that everyone should follow every day, but during the appliance treatment, brushing time and frequency will increase temporarily until the completion of the treatment.

6.6 Conclusion

The aim of this research was to explore patients' perceptions on eating difficulties during the course of orthodontic treatment by developing an instrument to determine ERQoL of orthodontic patients. Orthodontic patients were offered an opportunity to indicate their feelings and experiences about orthodontic treatment beyond the traditional biomedical model and through this exploration has expanded the existing knowledge of the researchers about ERQoL during orthodontic treatment. The findings of the qualitative study indicated the similarities of eating related difficulties (functional, emotional and psychological) across both age groups and both cultures. However some minor differences were found between the age groups and cultures which were mostly socially related issues.

The initial testing stage of the developed questionnaire determined its acceptability; validity and reliability. All participants completed the questionnaire fully and found it straightforward to complete. The subsequent qualitative assessment was focused to preserve the patient-centred notion of the study. Moreover the findings of both qualitative studies in Kurdistan and the UK were used as a confirmation tool for retaining some of the questions in the questionnaire due to their relevance and importance in the patients perspective. Therefore it would seem acceptable to use a translated version of the developed ERQoL questionnaire with Kurdish child orthodontic patients after validation of the translation and assessment of convergent validity.

The ERQoL questionnaire for orthodontic patients should be a useful tool for the orthodontic researcher, orthodontist and health care provider to get more information about eating difficulties

associated with treatment and could be used to provide targeted dietary advice according to the results of the questionnaire.

6.7 Implications of the Findings for Future Research

This study has produced a ERQoL questionnaire which has demonstrated acceptability, initial reliability and validity. The instrument is ready for further assessment and validation which should include assessment of patients with a range of different orthodontic appliances.

In the application of the ERQoL questionnaire it is important to consider that this questionnaire was formulated for UK children aged 11-16 years old. The Kurdistan qualitative study indicated similarities between the issues raised between the two cultures. However, it still needs to be validated with both face validity and convergent validity by performing a qualitative type of study before being applied in other cultures.

(Osborne and Costello, 2009) With regards to dietary instruction, it is important to clarify a number of details which may impact on its effectiveness. For example, who is best placed to deliver the dietary instruction, when is the best time for this, what level of detail should be included and how is it best delivered. This study did not explore these issues in detail, but these factors could improve the effectiveness of dissemination of the dietary information established in this work. The ways of delivering the instruction can be studied separately in a form of qualitative study by interviewing both orthodontists and patients to identify their experiences and perceptions.

The findings of this study also can be extended into another study to modify the questionnaire to be used with adult orthodontic patients. The appearance of the current ERQoL questionnaire tried to be child friendly by including simple language and cartoon faces for easier reference and to attract the children's attention. In the Kurdistan qualitative questionnaire most of the issues related to the eating difficulties were quite similar to the child orthodontic patients. Therefore whilst it is likely that a questionnaire covering similar topics could be used for adults, it is important to confirm this through future work.

Some social related eating difficulties were found to be different between the two age groups. More in-depth information about the impact of the orthodontic treatment on eating related social limitations could help provide more age specific advice on these issues, and this information could be gleaned through further qualitative research. Additionally it would be informative to look for gender variations in both age groups to explore the similarities and differences of social limitations of both genders during the treatment time.

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8 Appendices

Appendix A: Questionnaire after face validity

Appendix B: The UK ethical approval

Appendix B2: Kurdistan ethical approval

Appendix C1: The UK assent and consent form

Appendix C2: Kurdistan assent and consent form

Appendix D1: The UK Parent and Participant Information Sheet (face Validity and reliability stages)

Appendix D2: Kurdistan Parent and Participant Information Sheet (interviews and focus group)

Appendix E1: Interview topic guide

Appendix E2: Focus group topic guide

Appendix E3: Face validity topic guide

Appendix F: Framework analysis (Charting)

Appendix H: Questionnaire after testing reliability testing

Appendix I: Trainings (Qualitative study)

Eating with your brace

- There is no right or wrong answer.
- Thank you for participating in this study.
- Your answers will provide us with useful information about your experience of eating with your brace.
- This information will help us to improve the information we give to patients who are having their brace.

For answering the questions:

1. Read the questions carefully
2. put a cross (X) anywhere on the line under each questions
3. If you want to tell us more information write in the

Cloud

For Example

Before getting your brace, how good was the information your dentist told you about it?

Little information Very good information

0



10



He told me lots of information about the brace and gave me a leaflet.



Why? Can you explain...

From the start and afterwards

1. **Before getting your brace**, how did you think eating with a brace was going to be?

Difficult Easy

0



10



Why? Can you explain...

2. When you **first got your braces**, how did you find eating?

Difficult Easy

0



10

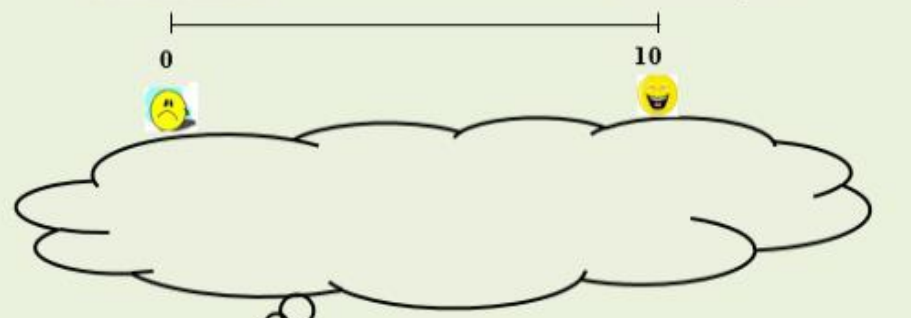


Why? Can you explain...

3. After your usual visits for tightening the brace what would happen to your eating?

Become difficult Remain easy

0 10

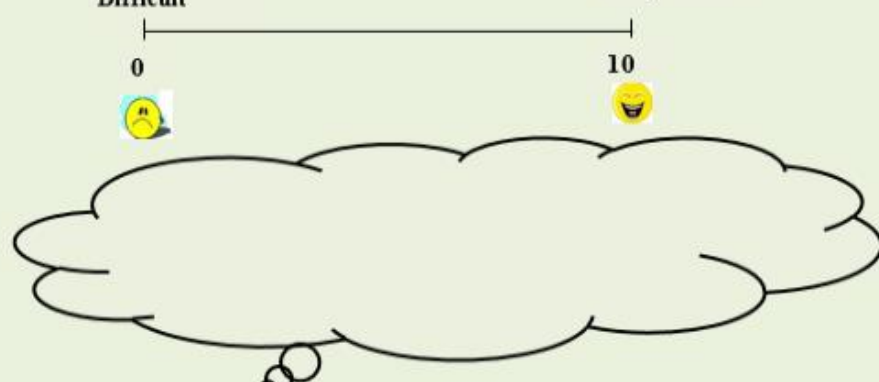


Why? Can you explain...

4. After you got used to your brace, how do you find eating?

Difficult Easy

0 10



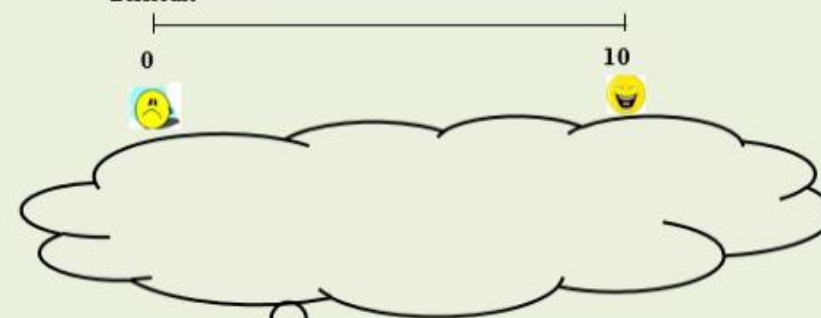
Why? Can you explain...

Eating with your brace

5. When eating with your brace, how do you find **BITING** foods?

Difficult Easy

0 10

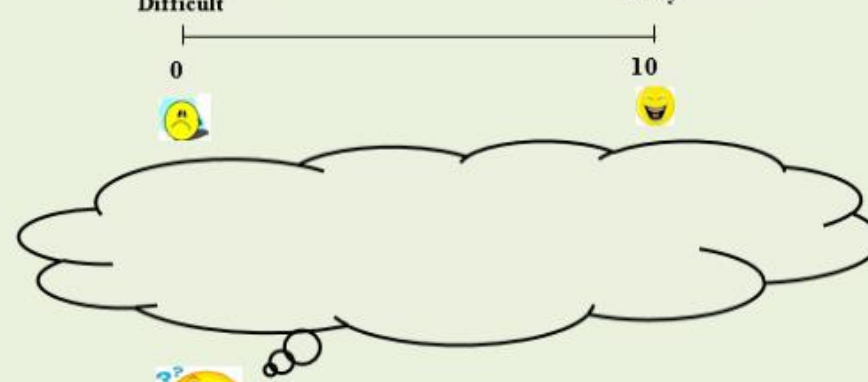


Why?

6. When eating with your brace, how do you find **SWALLOWING** foods?

Difficult Easy

0 10



Why?

7. When eating with your brace, how do you find **CHEWING** foods?

Difficult | Easy

0 | 10

Why?

8. When eating with your brace, how do you find a problem with foods or food particles **STICKING** to your brace?

Difficult | Easy

0 | 10

Why?

9. Are there any specific foods you find difficult to eat with your brace?

Which type of food(s)?

Why? Please explain...

Changes that happened

10. How long does it take you to eat with your brace, compared to when you didn't have it?

I eat slower | I eat quicker

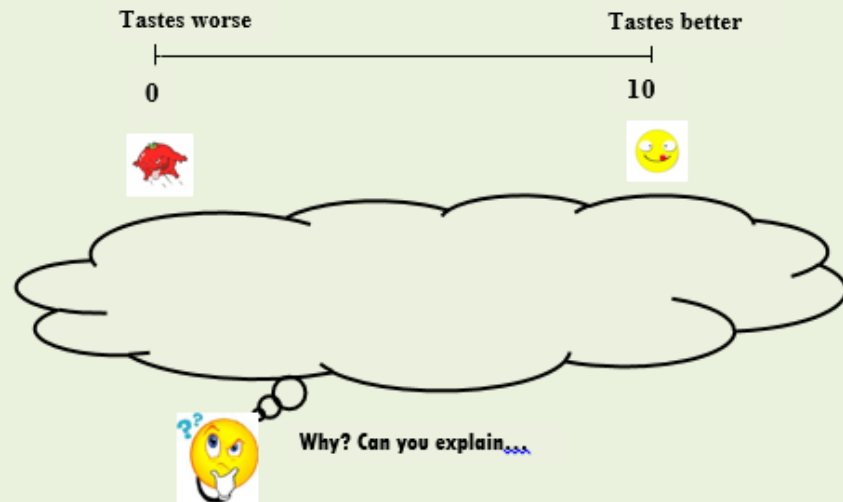
0 | 10

Why? Please explain...

11. Since wearing your brace how does your **food taste**?

Tastes worse Tastes better

0 10

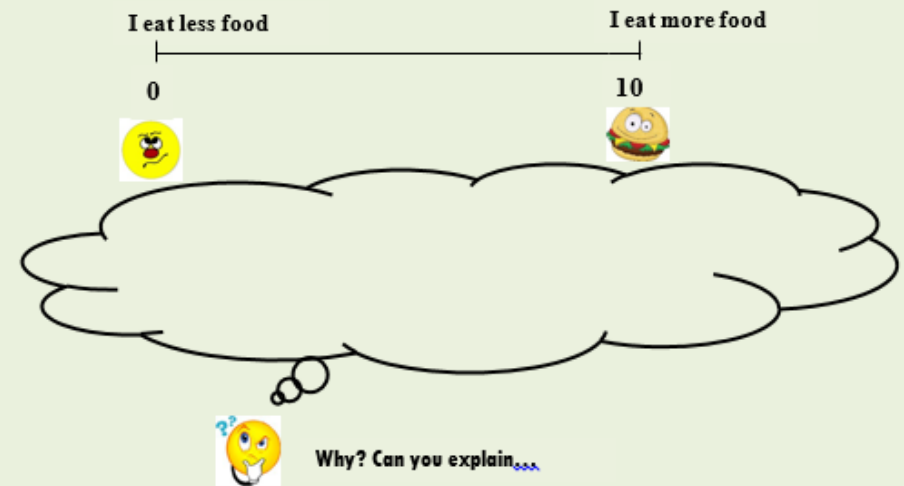


Why? Can you explain...

13. With your brace, **how much food do you eat** compared with before you had your brace?

I eat less food I eat more food

0 10



Why? Can you explain...

12. When wearing your brace, are there any **specific drinks** that **you avoid**?



Which drink(S)...?



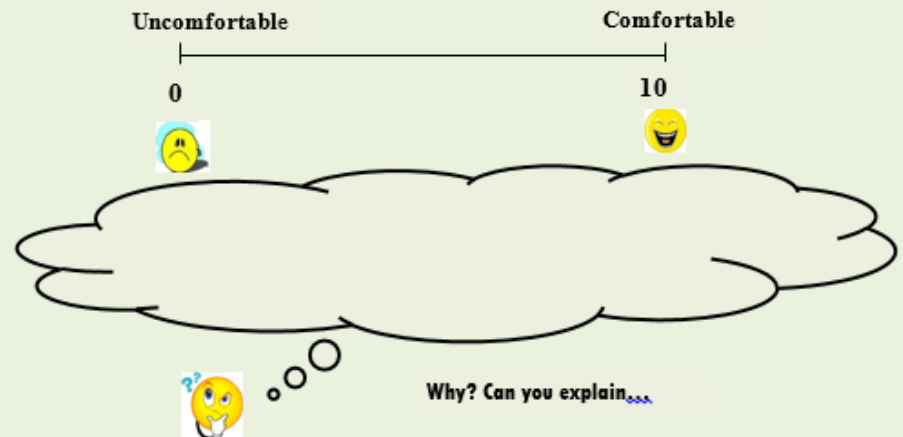
Why? Please can you explain?

Surrounding people and venue of eating

14. How do you feel when eating with your brace in front of your family?

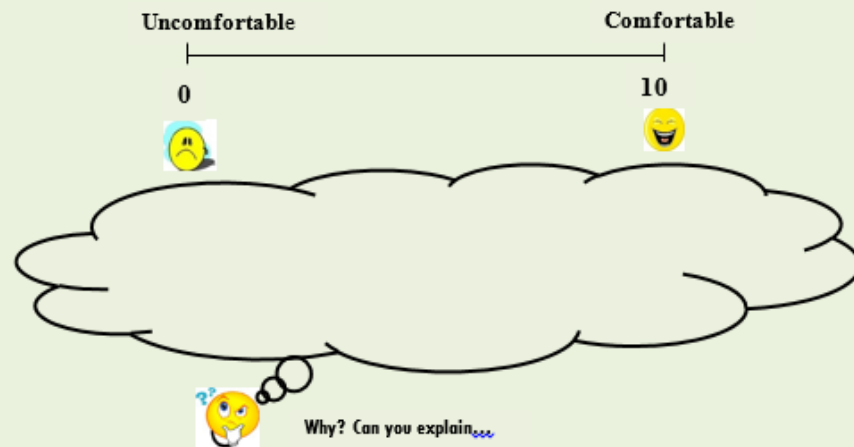
Uncomfortable Comfortable

0 10

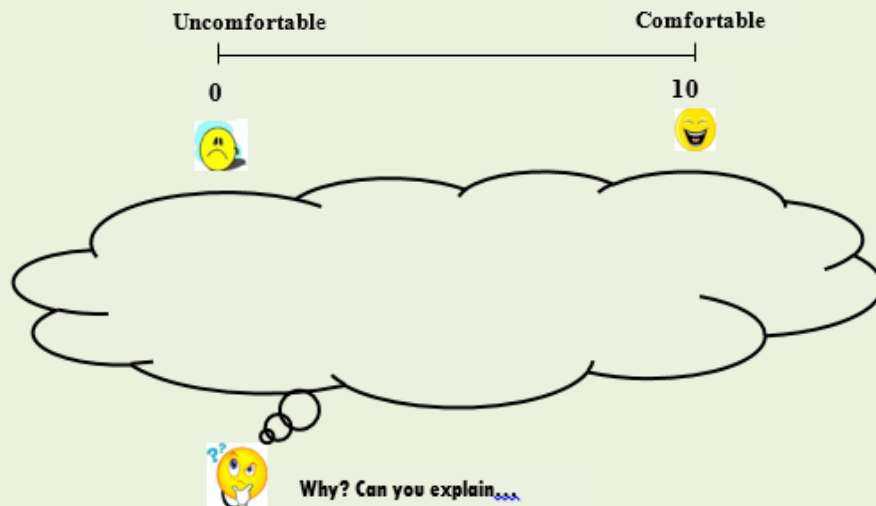


Why? Can you explain...

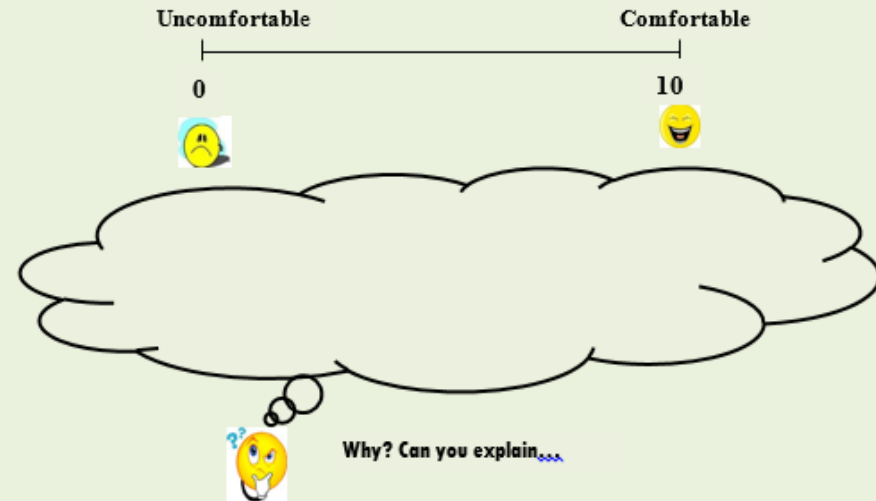
15. How do you feel when eating with your brace in front of your friends?



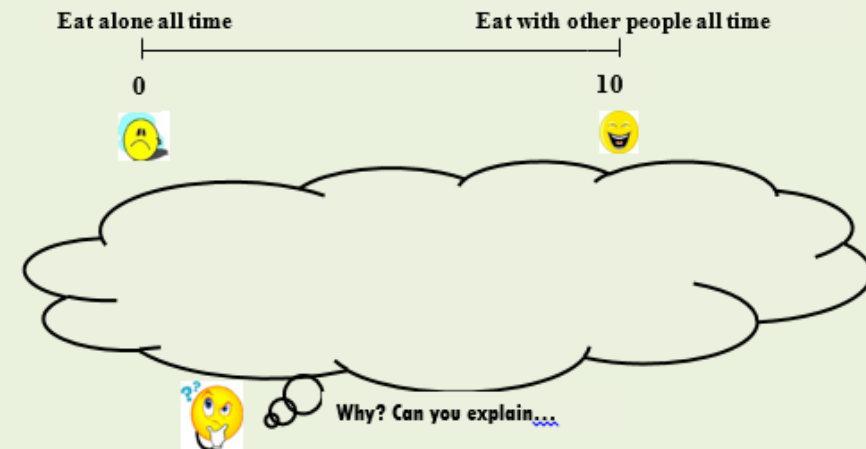
16. How do you feel when eating with your brace in presence of people you don't know?



17. How do you feel when eating with your brace when not in your own home? (For example at school, restaurant, friend's home.....)



18. When you have your brace, do you.....?

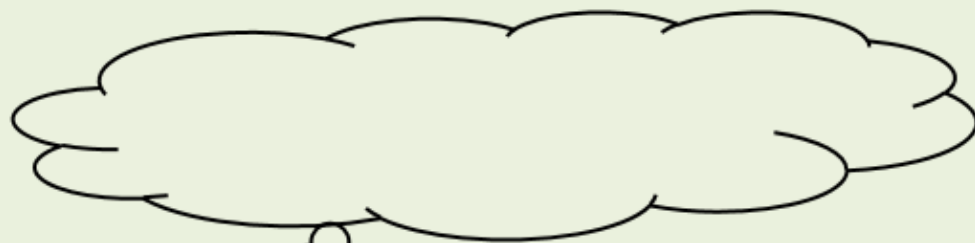


19. When you are eating with your brace do you.....?

Worry about what other people think

Don't care about what other people think

0 10



Why? Can you explain...

20. Since wearing your brace do you accept invitations to meals, parties.....?

Less often than before

More often than before

0 10



Why? Can you explain...

you and your dentist (orthodontist)

21. How helpful did you find the instructions your dentist gave you about eating with your brace?

Not at all

Very helpful

0 10



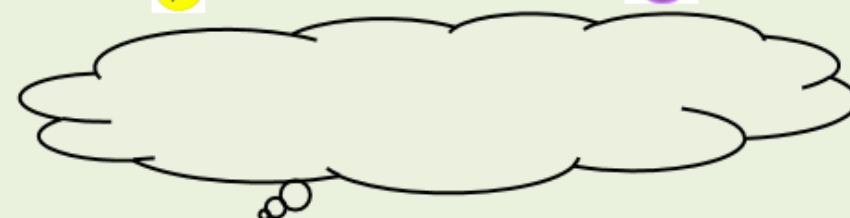
Why? Can you explain...

22. Did the advice of **your dentist** make you change the foods you eat?

Always

Never

0 10



Why? Can you explain...

23. How often do you avoid eating foods, if you are unable to brush your teeth/clean brace after meal?

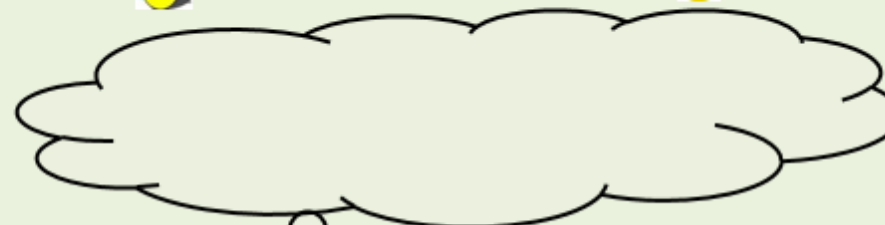
Very often
0
10
Never



Why? Can you explain

25. How enjoyable is eating with your brace?

Not enjoyable at all
0
10
Very enjoyable



Why? Can you explain...

Enjoyment of food

24. When wearing your brace, can you eat the foods you want to?

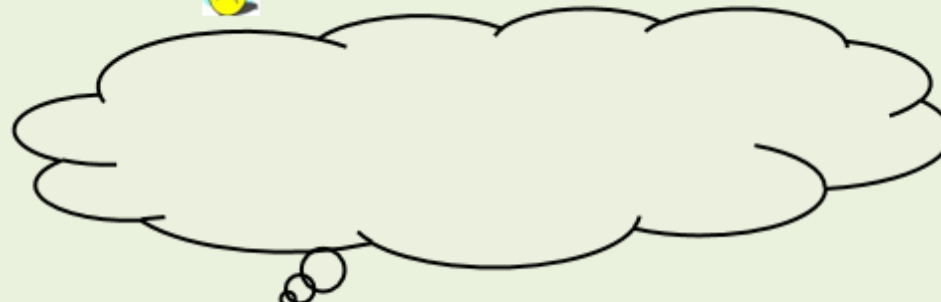
Never
0
10
Always



Why? Can you explain

26. Do you worry when eating/drinking with your brace?

Always
0
10
Never



Why? Can you explain...

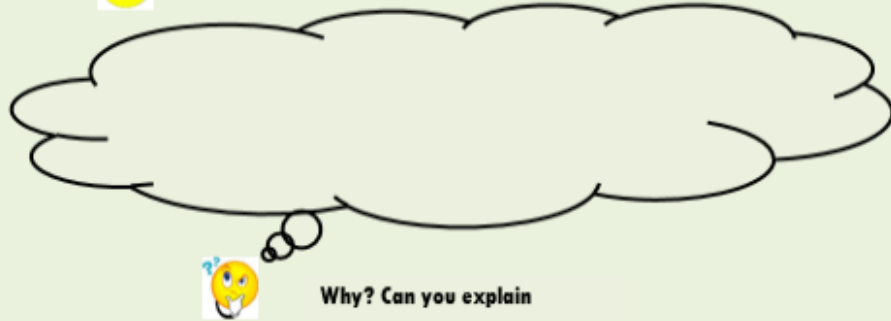
27. Does eating with your brace make you want to.....?

Totally stop wearing brace

Continue to wear brace

0

10



Why? Can you explain

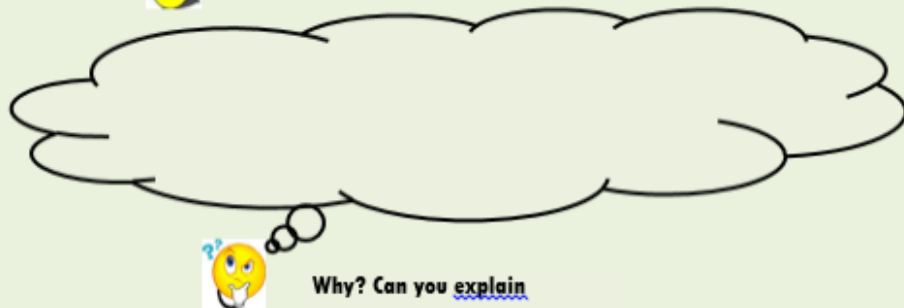
28. When you eat with your brace, do you feel.....?

Very embarrassed

Not embarrassed at all

0

10



Why? Can you explain

Please make any other comments about eating with your brace?



Appendix The UK ethical approval



NRES Committee North West - Liverpool Central

HRA NRES Centre - Manchester
3rd Floor
Barlow House
4 Minshull Street
Manchester
M1 3DZ

Telephone: 0161 625 7834
Facsimile: 0161 625 7919

02 May 2014

Dr Sarah Rolland
Clinical Lecturer in Child Dental Health (Orthodontics), Newcastle University
Newcastle University
University of Newcastle upon Tyne
Framlington Place
Newcastle upon Tyne
NE2 4BW

Dear Dr Rolland

Study title:	Developing a questionnaire on Eating Related Quality of Life for children undergoing orthodontic treatment.
REC reference:	14/NW/0315
IRAS project ID:	138772

The Proportionate Review Sub-committee of the NRES Committee North West - Liverpool Central reviewed the above application on 02 May 2014.

We plan to publish your research summary wording for the above study on the NRES website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the REC Manager Mrs Carol Ebenezer nrescommittee.northwest-liverpoolcentral@nhs.net.

Ethical opinion

On behalf of the Committee, the sub-committee gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

The Newcastle upon Tyne Hospitals

NHS Foundation Trust

SS/SB/JH

Royal Victoria Infirmary
Queen Victoria Road
Newcastle upon Tyne
NE1 4LP

15 May 2014

Dr Rye Mattick
Consultant Orthodontist
Dental Hospital
The Newcastle upon Tyne Hospitals NHS Foundation Trust
Royal Victoria Infirmary

Tel: 0191 233 6161
Fax: 0191 201 0155
www.newcastle-hospitals.nhs.uk

Dear Dr Mattick

Trust R&D Project:	7007
Title of Project:	The Impact of Orthodontic Treatment on Eating Related Quality of Life on different cultures and different age groups
Principal Investigator:	Dr Rye Mattick
Number of patients:	45
Funder (proposed):	no external funding
Sponsor (proposed):	The Newcastle upon Tyne Hospitals NHS Foundation Trust
REC number:	14/NW/0315
IRAS Project Code:	138772
First participant to be recruited by:	14 June 2014

After completing the necessary risk and site assessment for the above research project, The Newcastle upon Tyne Hospitals NHS Foundation Trust grants NHS Permission for this research to take place at this Trust dependent upon:


- (i) you, as Principal Investigator, agreeing to comply with the Department of Health's Research Governance Framework for Health and Social Care, and confirming your understanding of the responsibilities and duties of Principal Investigators by signing the Investigator Responsibilities Document. A copy of this document will be kept on file within the Joint Research Office.
- (ii) you, as Principal Investigator, ensuring compliance of the project with all other legislation and guidelines including Caldicott Guardian approvals and compliance with the Data Protection Act 1998, Health and Safety at Work Act 1974, any requirements of the MHRA (*eg* CTA, EudraCT registration), and any other relevant UK/European guidelines or legislation (*eg* reporting of suspected adverse incidents).
- (iii) where applicable, you, as Principal Investigator, should also adhere to the GMC supplementary guidance *Good practice in research* and *Consent to research* which sets out the good practice principles that doctors are expected to understand and follow if they are involved in research – see http://www.gmc-uk.org/guidance/ethical_guidance/5991.asp

The NIHR requires NHS organisations to recruit patients to CLRN Portfolio studies within 30 days from the date of this letter. The 30 day deadline for recruiting the first patient is therefore 14 June 2014.

Please note: the Department of Health 70-day bench mark requires recruitment within 70 days of a valid SSI submission. Therefore, recruiting within the NIHR 30 day target will ensure compliance with both targets.

Appendix B2: Kurdistan ethical approval

KURDISTAN REGIONAL GOVERNMENT
Council of Ministers
Ministry of Higher Education & Scientific Research
University of Sulaimani Presidency





رەسمى ھەرىجى كوردستان - عێراق
سەرۆكايەتى ئەنجومەنى وەزيران
وەزارەتى خوێندنى بالا و نوێژنە وەى زانستى
سەرۆكايەتى زانكۆى سلێمانى
واكرايەتى فاكەلتى زانستە پزىشكى يەكان

No: 39
Date: 9/6/2014

سكولى پزىشكى ددان / لیژنەى زانستى
School of Dentistry

ژمارە : ۲۹
پتەوت : ۶/۹ / ۲-۱۴ زایینی
۲۷۱۳ کوردی

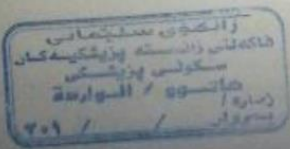
پۆ / سکولى پزىشكى / لیژنەى ناکار (Ethical Committee)
بابەت / پرۆتۆکۆل

دواى سلاوو ڕێژ.....
هەوێج ئەگەڵ نوسراوماندا پرۆتۆکۆلى توێژینهوهى بەرێژ (د.ادهم امین عبدالرحمن) بە ئاوانیشانى (مامۆستای یاریبەدەر) لە سکولهکەمان دەنێرین
بۆتوان ، بەمەبەستى پەرەمەندى ئە نجامدانى .
لەکەڵ ڕێژدا

ئاوانیشانى توێژینهوه کە :
The Impact of Orthodontic Treatment on Eating Related Quality of Life on different cultures and different age groups.
بە کوردی :
کارپگەریی چارەسەرى راستکردنەوهى ددان ئە سەر پەيوەندى خۇراك وەرگرتنى چۇنەبەتى ژيان ئە نىوان کەلتورە جىياوازەكان و چەند تەمەنىكى جىياوازدا .

پ . ی . د . ابراهيم سعيد کاظم
سەرۆكى لیژنەى زانستى سکول

لێژنەى ناکار
(Handwritten signature)



وێنەپەك پۆ:
لیژنەى زانستى سکول

[illegible]

Eating with your Brace



Assent form

Please put a circle
around one of the
answers

- | | | |
|----------|--|-----------------|
| 1 | Have you read the information sheet which tells you about this study | Yes / No |
| 2 | Have you talked to your parents about this study? | Yes / No |
| 3 | Do you know why we need your help with this study? | Yes / No |
| 4 | Do you know that you can stop taking part in this study at any time without the need of giving a reason? | Yes / No |
| 5 | Do you understand that your decision to take part or not take part will not affect your brace treatment? | Yes / No |
| 6 | Have all your questions been answered clearly? | Yes / No |
| 7 | Are you happy to take part in this study? | Yes / No |

If you are happy to take part, please write your name below

Name of Child

Date.....

Signature or child's name.

Name of person taking assent

Date.....

Signature

Parent / Guardian Consent Form

If you agree please
put your initial in the
boxes

1.	I have read and understood the information about the project, as provided in the Information Sheet, version _____ dated _____.	
2.	I have been given the opportunity to ask questions about the project and my child's participation.	
3.	I voluntarily agree for my child to participate in the project.	
4.	I understand my child can withdraw at any time without giving reasons and that I / my child will not be penalised for withdrawing nor will we be questioned on why my child has withdrawn.	
5.	The procedures regarding confidentiality have been clearly explained (e.g. use of names, pseudonyms, anonymisation of data, etc.) to me.	
6.	I understand that transcripts from the audio tapes and written notes from my interview may be looked at only by other members of the research team.	
7.	The use of the data in research, publications, sharing and archiving has been explained to me.	
8.	I understand that other researchers will have access to this data only if they agree to preserve the confidentiality of the data and if they agree to the terms I have specified in this form.	
10.	I agree to my child taking part in the study.	

Parent / Guardian:

Name of Parent / Guardian

Signature

Date

Researcher:

Name of Researcher

Signature

Date

☐



☐ کارێگه‌ری ئامیڤری پاستکردنه‌وه‌ی ددان له‌سه‌ر خواردن و چۆنیه‌تی ژیان

☐ پەزنامه‌ندینامه‌ی دایک و باوک

☐

☐ هه‌موو زانیاری بابته‌کانی ناو نامیلکه‌که‌م خۆینده‌وه‌ته‌وه‌ی لێی تیگه‌شتووم.

☐ ئەگەر هەر پرسیارێکم هه‌بوو بێت له‌سه‌ر به‌شداریکردنی منداڵه‌که‌م وه‌لامم دراوه‌ته‌وه‌.

☐ پزازی ده‌بم که منداڵه‌که‌م خۆبه‌خشانه‌ به‌شداری ئەم توێژینه‌وه‌یه بکات.

ئێوه ده‌زانم که منداڵه‌که‌م ده‌توانی‌ت هەر کاتێک که بیه‌وێت له‌ توێژینه‌وه‌که‌ پاشگه‌ز بیه‌یتوه‌ و ئەم‌ه‌ش هه‌یج کارێگه‌رییه‌کی له‌سه‌ر چاره‌سه‌ره‌که‌ی نابێت.

ئێوه‌ش تیگه‌شتووم که تۆماره‌ ده‌نگی و نوسراوه‌کان ته‌نها تیمی توێژینه‌وه‌که‌ به‌کاریدینی‌ت و له‌ جیگا‌یه‌کی پارێزراودا هه‌ڵده‌گیریت.

☐ من پەزنامه‌ندم به‌ به‌شداریکردنی منداڵه‌که‌م له‌م توێژینه‌وه‌یه‌دا

☐

☐ ناوی سیانی دایک یان باوک..... ئیمزا

☐ به‌روار



پێکهوتن نامه

ئایا نامیلکهی زانییه کانت خویندهوه که لایه نهکانی توێژینهوه که ی تیدابوو؟ به لێ نه خیر

ئایا له گه لدایک و باوکت له سه ر توێژینهوه که قسه تکردوه؟ به لێ نه خیر

ئایا ده زانی بۆچی پیوستان به یارمه تی تویه له م توێژینهوه دا؟ به لێ نه خیر

ئایا ده زانی که ده توانی توێژینهوه که به جیبه یلێت هه ر کاتی که به ته ویت؟ به لێ نه خیر

ئایا ده زانی که به یاردانت بۆ به شداریکردن یان نه کردن هیچ کاری گه ریه کی له سه ر چاره سه ری رستکردنه وه که ت نابیت؟ به لێ نه خیر

ئایا نه و پرسیارانیه که هتبه وه به روونی وه لامت دراوه ته وه؟ به لێ نه خیر

ئایا خوشحالی ت به به شداریکرن ت له م توێژینهوه دا؟ به لێ نه خیر

تکایه ئه گه ر ره زامه ندیت به به شداریکردن ناوی خۆت به ده ست و خه تی خۆت بنوسه

..... ناوی سیانی

به روار . . 2014



کاريگهري ئاميڤري پاستکردنهوهي ددان لهسهه خواردن و چۆنیهتی ژيان

په زامه ندينامه

هه موو زانياري باب ته كاني ناو ناميلكه كه م خوينده وه ته وه و ليي تيگه شتووم.

ئه گه هه پرسياريكه هه بوييت له سهه به شداري كردنم وه لامم دراوه ته وه.

پرازي ده بم كه خو به خشانه به شداري ئه م تويزينه وه يه بكه م.

ئه وه ده زانم كه ده توانيم هه كاتيک كه به وييت له تويزينه وه كه پاشگه ز بيمه وه و ئه مه ش هيچ

کاريگهرييه كي له سهه چاره سه ره كه م نابيت.

ئه وه ش تيگه شتووم كه تو ماره دهنگي و نوسراوه كان ته نها تيمي تويزينه وه كه به كاريدينييت و له

جيگايه كي پاريزراودا هه لده گيرييت.

من په زامه ندم به به شداري كردن له م تويزينه وه يه دا

..... ناوي سياني

ئيمزا

به رواه

Eating with a brace –Information Sheet for children and young people

Hello

You have been invited to take part in this study. Please read the information carefully and discuss it with your parent/s before you decide whether or not to take part. Your parents/guardian also has their own information sheet. If something is not clear, please ask us for further information.

Thank you for reading this information.

Introduction

We know that wearing a brace can make eating difficult. We want to know more about this and we are making a questionnaire to find out more. We can then use the results of this questionnaire to provide better information to patients with braces.

Before we ask lots of young people to fill in the questionnaire, we need your help to make sure that it all makes sense to young people.

Why have you been chosen to take part?

Because you are wearing a brace and you are 11-16 years old.

Do I have to take part?

No, it is up to you whether you choose to take part or not.

If you want to take part you will be given this information document to keep and we will ask you to sign a form which tells us you are happy to take part in the study.

Can I leave the study if I want to?

Yes, you can leave at any time and without the need to tell us why. It won't affect your treatment and your dentist will still look after your brace.

How long will it take?

We think that it will take about 45 minutes of your time, ideally after your usual brace check appointment.

What I have to do?

Firstly, we would like you to answer the questionnaire, then we would like to talk to you about what you thought of the questionnaire. We will probably talk about things like:

- Is it easy to read? Did it make sense?
- Would you like to change anything?
- Did you feel the questions applied to you / your experience of eating with a brace?

The discussion will be recorded, so that we don't forget what you have said. After the interview the whole discussion will be typed up. We will use this written record to help us remember what people said.

Who listens to my recording?

Only the researcher and his supervisors will listen to your recording and read your typed words.

All information will be kept strictly private. We won't tell your dentist, or anyone else, about what you have told us. All personal information like your name, names of family or friends or your dentist or anything else, which might recognise you will be removed from all written documents so that no-one can recognise you personally.

Contact for further information

If you have any questions or need further information about the study please feel free to contact:

Adham Abdulrahman (PhD student)

Email: a.a.abdulrahman@newcastle.ac.uk

Sarah Rolland (Clinical Lecturer in Orthodontics / Specialist Orthodontist / Dentist)

E-mail: s.l.rolland@newcastle.ac.uk

Professor Paula Moynihan (Professor in Nutrition)

E-mail: paula.moynihan@newcastle.ac.uk

All of these people can be written to at:

Level 4, School of Dental Sciences

Newcastle University, Framlington Place

NE2 4BW



Eating with Brace - Parent Information sheet

Your child is invited to take part in a research study. Before deciding whether or not you wish to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. If something is not clear, please ask us for further information.

Thank you very much for reading this.

Introduction

We know that wearing a brace affects the way we eat. We want to know more about this and have developed a questionnaire to explore the problems that patients with braces face with eating. We can then use the information from the questionnaire to provide better information to patients with braces.

Before we can use the questionnaire, we need your child's help to make sure that it all makes sense to young people.

What do my child needs to do?

We would like him/her to complete a questionnaire, and then talk to us about what he/she think of the questions & how easy it was to fill in.

Why have my child been chosen to take part?

Because he/she is wearing a brace and he/she is 11-16 years old.

Does he/she have to take part?

No, it is up to you to decide whether or not to take part.

If you want to take part will be given this information document to keep and we will ask you to sign a consent form, which tells us you are happy to participate. If you decide to take part and then you change your mind, you are still free to withdraw at any time and without giving a reason. Your child's brace treatment will not be affected by your acceptance / refusal to take part in this study.

What does it involve?

In total, we expect this will take about 45 minutes of your child's time, ideally after his/her routine brace check appointment.

Firstly, we would like him/her to spend a short time completing our questionnaire.

We will then ask your child some questions about the questionnaire, for example:

- Is it easy to read? Did it make sense?
- Would you like to change anything?
- Did you feel the questions applied to you / your experience of eating with a brace?

The discussion will be recorded but only the researcher and his supervisors will have access to the recordings. We record it in order to remember what has been discussed. After the interview, the recording will be listened to carefully and every word that both your child and the interviewer say will be typed down. We use this written record, to help us remember what people said.

Will all information be kept confidential?

All information will be kept strictly confidential. We won't tell his/her dentist, or anyone else, about what he/she tell us. His/her questionnaire answer, the recording of his/her interview and the written record will be given a code to make sure that no-one outside of the research team know who you are. All information written / recorded will be stored securely to make sure that only the research team can access them.

All personal information – your child's name, names of family or friends, or your dentist - or anything else, which might identify you, will be removed so that no one can identify you personally.

Contact for further information

If you have any questions or need further information about the study please do not hesitate to contact:

Adham Abdulrahman (PhD student)

Email: a.a.abdulrahman@newcastle.ac.uk

Sarah Rolland (Clinical Lecturer in Orthodontics / Specialist Orthodontist)

E-mail: s.l.rolland@newcastle.ac.uk

Professor Paula Moynihan (Professor in Nutrition)

E-mail: paula.moynihan@newcastle.ac.uk

All of these people can be written to at:

Level 4

School of Dental Sciences

Newcastle University

Framlington Place

NE2 4BW



Eating with your Brace –Information Sheet for children and young people

Hello

You have been invited to take part in this study. Please read the information carefully and discuss it with your parent/s before you decide whether or not to take part. Your parents/guardian also has their own information sheet. If something is not clear, please ask us for further information.

Thank you for reading this information.

Introduction

We know that wearing a brace can make eating difficult. We want to know more about this and we are making a questionnaire to find out more. We can then use the results of this questionnaire to provide better information to patients with braces.

Before we ask lots of young people to fill in the questionnaire, we need your help to make sure that it all makes sense to young people.

Why have you been chosen to take part?

Because you are wearing a brace and you are 11-16 years old.

Do I have to take part?

No, it is up to you whether you choose to take part or not.

If you want to take part you will be given this information document to keep and we will ask you to sign a form which tells us you are happy to take part in the study.

Can I leave the study if I want to?

Yes, you can leave at any time and without the need to tell us why. It won't affect your treatment and your dentist will still look after your brace.

How long will it take?

We think that each time you fill in the questionnaire it will take about 15 minutes of your time, ideally after your usual brace check appointment.

What do I have to do?

Firstly, we would like you to complete our questionnaire whilst you are at the Dental Hospital for your usual brace appointment.

Two weeks later, we will send the same questionnaire to your home and would like you to complete it again. We will include a stamped addressed envelope so it is easy for you to send it back to us.

We are doing this because we want to know whether people's answers to the questionnaire change over a short period of time.

Who looks at my answers?

Only the researcher and his supervisors will look at your answers.

All information will be kept strictly private. We won't tell your dentist, or anyone else, about what you have written. All personal information like your name, names of family or friends or your dentist or anything else, which might identify you will be removed from all written documents so that no-one can recognise you personally.

Contact for further information

If you have any questions or need further information about the study please feel free to contact:

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Email: a.a.abdulrahman@newcastle.ac.uk

Sarah Rolland (Clinical Lecturer in Orthodontics / Specialist Orthodontist / Dentist)

E-mail: s.l.rolland@newcastle.ac.uk

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All of these people can be written to at:

Level 4, School of Dental Sciences

Newcastle University, Framlington Place

NE2

Eating with your Brace – Parent Information sheet



Your child is invited to take part in a research study. Before deciding whether or not you wish to take part it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. If something is not clear, please ask us for further information.

Thank you very much for reading this.

Introduction

We know that wearing a brace affects the way we eat. We want to know more about this and have developed a questionnaire to explore the problems that patients with braces face with eating. We can then use the information from the questionnaire to provide better information to patients with braces.

Before we can use the questionnaire, we need your child's help to make sure that it all makes sense to young people.

What does my child need to do?

We would like your child to complete a simple questionnaire twice – once while he/she is at the Dental Hospital for your routine appointment, and again two weeks later at home.

Why has my child been chosen to take part?

Because he/she is wearing a brace and he/she is 11-16 years old.

Does he/she have to take part?

No, it is up to you to decide whether or not to take part.

If you want to take part will be given this information document to keep and we will ask you to sign a consent form, which tells us you are happy to participate. If you decide to take part and then you change your mind, you are still free to withdraw at any time and without giving a reason. Your child's brace treatment will not be affected by your acceptance / refusal to take part in this study.

What does it involve?

We expect that each time he/she fills in the questionnaire this will take about 15 minutes of your time.

Firstly, we would like your child to complete our questionnaire whilst he/she is at the Dental Hospital for his/her routine brace appointment.

Two weeks later, we will send the same questionnaire to your home and would like him/her to complete it again. We will include a stamped addressed envelope so it is easy for you to send it back to us.

We are doing this because we want to know whether people's answers to the questionnaire change over a short period of time.

Will all information be kept confidential?

All information will be kept strictly confidential. His/her questionnaires will be given a code to make sure that no one outside of the research team knows who you are. All information will be stored securely to make sure that only the research team can access them.

Contact for further information

If you have any questions or need further information about the study please do not hesitate to contact:

Adham Abdulrahman (PhD student)

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نامیلکه‌ی زانیاری به‌شداریبووان

کاریگه‌ری ئامیڤری راستکردنه‌وه‌ی ددان له‌سه‌ر خواردن و چۆنیه‌تی ژیان

خۆشحاڵین به به‌شداری کردنت له‌م توێژینه‌وه‌دا بۆ وه‌ده‌ست خستنی زانیاری زیاتر له‌ سه‌ر کاریگه‌ری ئامیڤری راستکردنه‌وه‌ی ددان له‌سه‌ر خواردنی گه‌وره و تازه‌ پیگه‌شتوان.

ئهم نامیلکه‌ی نوسراوه بۆ تۆی به‌پێژ بۆ پێدانی زانیاری گونجاو له‌سه‌ر ئهم توێژینه‌وه‌یه و به‌رچاوت زیاتر پوئتر بکات له به‌شداری کردنت له توێژینه‌وه‌که‌دا.

ئایا ئامانجی ئهم توێژینه‌وه‌یه چی‌یه؟

به‌شیکی زۆری ئهو نه‌خۆشانه‌ی که وه‌رده‌گیریت بۆ راستکردنه‌وه‌ی ددان بریتی‌یه له‌و نه‌خۆشانه‌ی که ته‌مه‌نیان ته‌ نیوان 11- 16 سالی‌دایه. به‌لام له‌ کوردستان به‌ هۆی تازه‌یی و که‌می پسیڤۆری چاره‌سه‌ری راستکردنه‌وه‌ی ددان زۆریک له‌و هاوولا‌تیانه‌ی که پێویستیان به‌م چاره‌سه‌ره هه‌بووه نه‌یان‌توانیوه له‌و کاته گونجاوه‌دا ئامیڤری راستکردنه‌وه دابنێن. له‌به‌ر ئهو هۆیانه به‌ریکی به‌رچاو نه‌خۆشی ته‌مه‌ن گه‌وره به‌رچاو ده‌که‌وێت. ئێمه ده‌مانه‌وێت که فۆرمیکی زانیاری گونجاو دروست بکه‌ین که نه‌خۆشه‌کانی راستکردنه‌وه‌ی ددان به‌شدارین له‌ دروستکردنی‌دا و به‌ته‌واوی بۆ ئه‌وان ئارسته‌که‌راو بێت. به‌پێژت له‌ نیوان ته‌مه‌نی 20- 25 سالی‌دایت و ئامیڤری راستکردنه‌وه‌ی ددان به‌ کارده‌هینی‌ت. بۆ گومان تۆ ئه‌زمونیکت هه‌یه له‌گه‌ڵ ئهم چاره‌سه‌ره‌دا و ئێمه‌ش ده‌مانه‌وێت زیاتر بزانی له‌سه‌ر کایگه‌ریه‌یه‌ باش و خراپه‌کانی ئهم چاره‌سه‌ره له‌ کاتی خواردن دا.

ئایا پێویسته به‌شداری بکه‌یت؟

به‌شداریکردن له‌م توێژینه‌وه‌دا خۆبه‌خشانه‌یه ده‌که‌وێت سه‌ر خۆت ئایا ده‌ته‌وێت به‌شداری بکه‌یت یا نا. ئێمه باسیکی ئهم توێژینه‌وه‌یه بۆ به‌پێژت ده‌که‌ین و هه‌موو پرسیاریکی پهیوه‌ندیدار وه‌لام ده‌ده‌ینه‌وه و پاشان داوات لێ ده‌که‌ین که فۆرمی ئاره‌زووی به‌شداریکردنتان ئیمزا بکه‌ن. تۆ به‌ته‌واوی ئازادی له‌وه‌ی که رات بگۆڕیت و پاشگه‌ز ببیته‌وه له به‌شداریکردن ته‌نانه‌ت پاش ئیمزاکردنه‌که‌ش. هه‌روه‌ها هه‌یچ جو‌ره

پرسىيارىكت لى ناكريئت سەبارەت بە ھۆكارى پاشگەزىبونەۋەكەت و چارەسەرى راستىكرىدەنەۋەكەش بە ھىچ جورىك كاريگەرى لەسە نايىت ئەگەر ھاتوو ئارەزوى بەشدرىكرىدەنەۋەبوو.

تويژىنەۋەكە چى لە خو دەگرىت؟

بەريئت بانگھيشت دەكرىيت بۇ ئامادە بوون لە گروپكى وتويژدا لەگەل ھەندىك لە ھاوتەمەنەكانت (6-8 كەس) كە ئەوانىش ھەمان جورە چارەسەريان ھەيە (راستىكرىدەنەۋەى ددان). ئەم وتويژە زۆر ھيىمانەيە و ھەمووان ھاندەدرىن كە بىرپاۋ ئەزموونەكانى خويان بخەنە پوو. ئەم وتويژە لە كۆليژى پزىشكى ددان لە زانكۆى سلىمانى ئەنجام دەدرىت.

وتويژەكان تۆمار دەكرىن بۇ ئەۋەى كە خالە گرىنكەكان لە بىر نەچچتەۋە و پاشان تۆمارە دەنگىەكان دەنوسرىتەۋە بەبى ناۋھىنانى بەشداربووان لەبەرئەۋەى ناۋەكان بە نھىنى و بە متمانەۋە لە لاى تويژە بمىنىتەۋە. لە دواى ئەم وتويژە بەكۆمەلە ھەندىك لە بەشداربووان دوبارە بانگھيشت دەكرىن بۇ ئامادەبوون لە گفتوگۆيەكى دوو بە دوو لەگەل تويژە دا بۇ پوونىكرىدەنەۋەى ھەر بابەتتىكى دىكەى گرىنگ بە دورودرىژى. ئەم بەشدارىكرىدەنەش دووبارە خۇبەخشەنەيە و دەكەويتە سەر بەشداربوو ئايا دەيەويت بەشدارى بكات يان نا. ھەرۋەھا گفتوگۆ و وتويژەكان لە كاتىكدا پىكدەخريئت كە بە ھىچ جورىك كاتى خويىندەن و ئيش و كارت نەگرىت. ھەر يەكەك لە بەشداربووانى ئەم تويژىنەۋەيە سىتتىكى تەندروستى دەم و ددانى پىدەبەخشريئت ۋەك سوپاسگوزارىيەك بۇ ئامادەبوونى لەم تويژىنەۋەيەدا.

چى پوو دەدات كاتىك تويژىنەۋەكە كۆتايى پى دىت؟

لە كۆتايىدا تويژىنەۋەكە پرسنامەيەك بەرھەم دەھيىنريئت كە دەتوانىت بەكار بەيىنريئت بۇ دىيارىكرىدنى كاريگەرى ئامىرى راستىكرىدەنەۋەى ددان لە سەر خواردن و چۆنيەتى ژيانى ئەو كەسانەى كە ئەم چارەسەريان بۇ دەكرىت. ئەم تويژىنەۋەيە برىتتىيە لە بەشيك لە خويىندى دكتورا لە بوارى زانستى راستىكرىدەنەۋەى ددان كە ئەنجام دەدرىت لە زانكۆى نيوكاسل - بەرىتانىا. ئەنجامەكانى ئەم تويژىنەۋەيە بە شىۋەى نوسراۋ گوتراۋ نىشانى چەندىن پسپۇرى دىكەى راستىكرىدەنەۋەى ددان و تەندروستى دەم و ددان دەدرىت. ھەرۋەھا لە كۆنفرانس و گوڤارى زانستىدا بلاۋ دەكرىتەۋە. يەككى دىكە لە ئەنجامەكانى ئەم تويژىنەۋەيە برىتتىيە لە پىكخستنى نامىلكەيەكى ستاندارد بۇ ئەو ئامۇزگارىيانەى كە پىويستە پزىشكى راستىكرىدەنەۋەى ددان بىدات بە نەخۆشەكانى بۇ ئۈەى بە شىۋەيەكى تەندروست مامەلە لەگەل ئامىرى راستىكرىدەنەۋەكەدا بىكەن.

ئايا بەشدار بوونى نەخۆشەكان بە متمانەۋە دەپارىژريئت؟

ھەر زانىارىيەك كە پەيۋەندى بە تۆۋە ھەيىت زۆر بە نھىنى و متمانەۋە دەپارىژريئت. ھەر بەشداربوويەك كۆدىكى تاييەتى بۇ دادەنريئت كە تەنھا تىمى تويژىنەۋەى دكتوراكە دەزانن واتاى چىيە. كۆدەكەش

❑كى به ئەنجامەكانى ئەم تويژىنەۋەدا دەچىتەۋە؟

ئەم تويژىنەۋەيە بريتىيە لە بەشىك لە تويژىنەۋەي پلەي دكتورا كە ئەنجامەكانى لە لايەن سى
كەسى پىسپۇر لە بۋارەكەدا سەرپەرشتى دەكرىت. پاشان ھەموو سالىك بە دريژايى ماۋەي
خويندەكە ئەنجامەكان و تويژىنەۋەكە دەخرىتە بەردەم ليژنەيەكى ھەلسەنگاندنى شارەزاۋە.
زۆر سوپاس بۆ خويندەۋەي ئەم زانىاريانە و ئەگەر ھەر پرسىيارىكت ھەبوو لە ھەر لايەنيكى
تويژىنەۋەكە بە خوشحالييەۋە ۋەلامت دەدرىتەۋە.

❑بۆ زانىارى زياتر دەتوانىت پەيوەندى بكەيت بە تويژەر : د. ادھم امين عبدالرحمن

ئيمەيل:

a.a.abdulrahman@ncl.ac.uk

يان بە ژمارە تەلەفونى 07480691312



نامیلکە ی زانیاری دایک و باوکی



بەشداریبوو

کارێگەری ئامیڤری راستکردنەوهی ددان لەسەر خواردن و چۆنیەتی ژیان

خۆشحالیڤ بە بەشداری کردنت لەم توێژینەوهدا بۆ وەدەست خستنی زانیاری زیاتر لە سەر

کارێگەری ئامیڤری راستکردنەوهی ددان لەسەر خواردنی گەورە و تازە پیگەشتوان.

ئەم نامیلکە یە نوسراوە بۆ دایکان و باوکان بۆ پێدانی زانیاری گونجاو لەسەر ئەم توێژینەوهیە و بەرچاوتان پوتتر بکات لە بەشداری پیکردنی منداڵەکەت.

ئایا ئامانجی ئەم توێژینەوهیە چییە؟

بە شیکێ زۆری ئەو نەخۆشەکانی کە وەردەگیرێت بۆ راستکردنەوهی ددان بریتی یە لەو نەخۆشەکانی کە تەمەنیان تە نیوان 11- 16 سالی دایە. ئیمە دەمانەویت کە فۆرمیکێ زانیاری گونجاو دروست بکەین کە نەخۆشەکانی راست راستکردنەوهی ددان بەشداریڤ لە دروستکردنی دا و بە تەواوی بۆ ئەوان ئارستەکرا و بیّت. منداڵەکەت لە نیوان تەمەنی 11- 16 سالی دایە و ئامیڤری راستکردنەوهی ددان بە کار دەهینێت. بۆ گومان منداڵەکەت ئەزمونیکی هەیه لەگەڵ ئەم چارەسەرەدا و ئیمەش دەمانەویت زیاتر بزانیڤ لەسەر کایگەریە باش و خراپەکانی ئەم چارەسەرە لە کاتی خواردن دا.

ئایا پێویستە منداڵەکەت بەشداری بکات؟

بەشداریکردن لەم توێژینەوهدا خۆبەخشانە یە و دەکەویتە سەر خۆتان ئایا دەتانەویت بەشداری بکەن یا نا. ئیمە باسیکی ئەم توێژینەوهیە بۆ منداڵەکەت دەکین و هەموو پرسیاریکێ پەییوەندیاری وەلام دەدەینەوه و پاشان داوا دەکەین کە هەردووکتان (تۆ و منداڵەکەت) کە فۆرمی ئارەزووی بەشداریکردنتان ئیمزا بکەن. ئیوه بەتەواوی ئازادن لەوهی کە پاتان بگوڤن و پاشگەز ببنەوه لە بەشداریکردن تەنانەت پاش ئیمزاکردنەکەش. هەرهەها هیچ جوړە پرسیاریکت لی ئاکرت سەبارەت بە هۆکاری پاشگەزبوونەوهکەت و چارەسەری

ھەر زانىيارييەك كە پەيوەندى بە مندالەكەتەو ھەبىت زۆر بە نەينى و متمانەو دەپاريزىرئىت .
ھەر بەشداربوويەك كۆدىكى تايبەتى بۇ دادەنرئىت كە تەنھا تيمى تويزئىنەو ەى دكتوراكە دەزانن
واتاى چيىيە . كۆدەكەش برىتيىيە لە زانىارى لەسەر ناو و رەگەز و تەمەن و جۆرى ناميرى
راستىكرەنەو ەكە . كاتىك كە گفتوگۆكان دەنوسريئەو ە ئەو كۆدانە بەكار دەھيئىرئىت لە جياتى
ناو ە راستەقىنەكە . ھەموو داتا و زانىاريىيە كۆكراو ەكان لە شۆيئىكى نەينى و پاريزراودا
ھەلدەگيرئىت و لە كۆتايى تويزئىنەو ەكەدا لە ناودەبردرئىت .

چى ەو دەدات ئەگەر مندالەكەم لە تويزئىنەو ەكە پاشەكشيى كرد؟

مندالەكەت نازادە لەو ەى كە پاى بگۆرئىت لەبارەى بەشداريكرەنى لەھەر كاتىكدا ، تەنانەت لە
دواى ئيمزا كردنى رەزامەندى نامەكەش . ھەرەو ھا ھيچ جۆرە پرسىاريكى لى ناكۆت سەبارەت
بە ھۆكارى پاشگەزبوونەو ەكەى و چارەسەرى راستىكرەنەو ەكەش بە ھيچ جۆرىك كاريگەرى
لەسە نابىت ئەگەر ھاتوو ئارەزوى بەشدريكرەنى نەبوو .

چى ئەكەيت ئەگەر ھاتوو تيبينىت ھەبوو لەسەر تويزئىنەو ەكە؟

ئەگەر ھەر تيبينىيەكت ھەبوو لەسەر ھەر لايەنىكى تويزئىنەو ەكە دەتوانىت پرسىيارەكانت
ئاراستەى تويزئەر بکەيت . ئەويش بە تەواوى ئامادەى وەلام دانەو ەت دەبىت . (ھۆكارەكانى
پەيوەنيكرەن لەگەل تويزئەر لە كۆتايى ئەم نامىلكەيدا دەخريئەروو) .

ئايا پزىشكى تايبەتى راستىكرەنەو ەى ددانەكەت ئاگادار دەكرئەو ە سەبارەت بەم
تويزئىنەو ەى؟

پزىشكە تايبەتەكەت لە تويزئىنەو ەكە ئاگادارە بەلام ئەو بابەتانەى كە مندالەكەت لەم تويزئىنەو ەدا
ووتوئەتى وخستويەتبيە روو بە نەينى لە لاي تويزئەر دەمئىئەتەو ە . بەلام ئەگەر ھاتوو بابەتەكە
گرنگ بوو بۆچارەسەرى راستىكرەنەو ەكە يان پەيوەندى راستەوخوى ھەبوو لەگەل
تەندروستى بەشداربوو ئەوا پيى رادەگەيەنرئىت .

كى بە ئەنجامەكانى ئەم تويزئىنەو ەدا دەچئەو ە؟

ئەم تويزئىنەو ەىيە برىتيىيە لە بەشيك لە تويزئىنەو ەى پلەى دكتورا كە ئەنجامەكانى لە لايەن سى
كەسى پسپۆر لە بوارەكەدا سەرپەرشتى دەكرئىت . پاشان ھەموو سالىك بە دريژايى ماو ەى
خويندەكە ئەنجامەكان و تويزئىنەو ەكە دەخريئە بەردەم ليژنەيەكى ھەلسەنگاندنى شارەزاو ە .
زۆر سوپاس بۆ خويندەو ەى ئەم زانىاريانە و ئەگەر ھەر پرسىاريكت ھەبوو لە ھەر لايەنىكى
تويزئىنەو ەكە بە خوشحاليىو ە وەلامت دەدرئەو ە .

□ بۇ زانىارى زياتر دەتوانيت پەيوەندى بکەيت بە تويۇرەر : د. ادھم امين عبدالرحمن

ئيمەيل:

a.a.abdulrahman@ncl.ac.uk

□ يان بە ژمارە تەلەفونى 07480691312

Appendix E1 Interview topic guide

Eating with brace

Interview topic guide

Introduction

Ground rule: No right or wrong answer.

If you don't like any of the questions you can skip it.

You can discuss any questions as much as you like.

Your conversation will be recorded, transcribed and will be used for analysis.

All recordings will be kept strictly confidential and your real name will not be used in transcription.

Do you have any question about the study?

Thoughts about the brace prior to treatment

- Can you tell me how did you make a decision to have a brace?

Was it them, their dentist or a family member who first suggested?

- Before getting your brace, what did you think it would be like to have a brace?
- What's the first thing that you thought to be difficult?

If the answer other than eating, what about eating? I want to know more about it.

Experiences with braces

- When you first got the brace what was it like?
- Were eating difficulties like what you were expected to be? Why?
- Tell me more about your eating during the first days after inserting your brace?
- **How you solved that situation?**
- Which type of food you mostly avoided?
- Can you tell me about drinking with the brace?
- Which types of drink you mostly avoided? Why?

- Have you changed the habit of eating? In which way?
- Have you ever thought to discontinue your treatment because of eating problems?
- When you had such thought? Why?
- What about your feeling when you eat in front of other people?
- How is your feeling when you eat in front of other people or your friend outside in public spaces such as restaurant, school or university?
- Have you ever refused a special type of food due to the difficulties of such type of food in an invitation or in your relative house?

Information about braces

- ❖ How would you advise your friend if she/he recently gets a brace?
- ❖ What information did your (dentist, orthodontist) give you about braces
 - Did this include information about eating?
 - What information did they give you about eating?
 - What was the focus point of the instruction?
 - Do you think your dentist's instructions about eating were helpful?
 - Can you give me a list of food that you avoided because they were included in the instruction?
 - Do like to add anything else to those instructions?
 - Which type of instruction mostly do you like? Verbal, writing or other formant (audio or video).
 - Which of them are more important? Why?
 - Did the instructions push you to avoid some foods that you think were not necessary to avoid? How?
 - How do you think about the time of instructions?
 - When it is the best time to give the instructions?
 - Do you think your orthodontist instruct you because he is more worried about his work (brace itself) or he concerns about your quality of life in eating with the brace?
 - Do you believe re-instruction by your orthodontist makes any change?
 - Have you they obtained any information about braces from other sources (friends/family/internet)?

- If you are a dentist how would you advice your patients?

Changes due to brace

- Do you think your acquired habits of eating to remain even after the end of treatment?
- Do you know, what is the most common cause of eating difficulties with brace?
- Everyone has a favorite food, have you lost your favorite food because of the brace?
- What about the speed of eating, is it changed or not?
- Do you realise that you are the last one who finishes his/her meal?
- How do you feel when you face such problem?
- Are you thinking differently about food and eating because of the brace?
- Can you eat as much as you like? Why?
- What would be an alternative when you cannot eat properly?
- Do you eat something that you don't like?
- Have you increased your meal frequency?
- Can you tell me about the taste of food? Is it changed or not? If "changed", what may be the cause?
- Has your body weight been changed since the beginning of the treatment?
- If someone before the brace insertion tell you that, "brace makes lots of eating problems", do you still agree to receive the treatment? Why?
- What about the oral hygiene measures, is it making you to avoid certain foods?
- Do you have a friend or relative with braces?

If Yeas, does she/he the same eating problems like you?

If No, why she/he doesn't have such problems?

Red: To be deleted

Blue: To be added

Green: The order to be changed

Appendix E2: Focus group topic guides

Focus group topic guides

Eating with braces

Introducing the researcher and moderator to the participants

Introducing the participants to each other

Brief introduction to the study project

Ground rules No right or wrong answer

Everyone can share and discuss the topics

Seating plan: round table with two microphones, card, pen, paper in front of each participant.

Activity

1. On a card, write your favourite food and the best food you missed because of your brace
2. The best thing and worst thing in eating with braces

Open questions

- Before inserting the brace, how was your prediction toward the eating problem?
 - Now, after insertion, does your prediction come in truth or not?
 - What about the first day after insertion
1. Was eating the eating major problem
 2. Can anyone remember the first time you tried to eat something but you couldn't because of the brace?
 3. Have you returned back to normal?

If No, why?

If Yes, how long it takes?

On the white board, together write some important eating difficulties that you have faced during the course of treatment.

Then together vote for the important one.

Activity

Appendix F: Framework analysis (Charting)

[illegible]

K 14 FF interview kazya	زۆر له سمرتا باشترم ئيسنا نمتوانم زۆر شت بخۆم بهلام همر ومك جارن نيه.	ئىيىسىنا كە ئىيشۆم ھەر ھەست ئەكەم ئىيشۆم ددانەكانم زېرە، جارن صاف ئىچۆم، لەبەر ئۆتە دوای ھەموو خواردنك دوو سا جار ئىيشۆم	ئاروى طەورە قورسە تەنھا ھى بضووك ئەطرم. گۆشتم بمتواومنى واز لى ھىناوہ.
K 24 FF	ئىسىنا لەبەر تەقويم ەكە ھىض خواردنك نىيە كە بە ھىض جۆرىك ئىخۆم مەطەر خۆم ھازم لا نەبىت	ھەر شتىكم خواردىت يەكسەر ددانم شوردو لەبەر ئۆتە ھىض شتىكى ئىدا نەمىننەتە. ب ە راست نەش ناخۆشە زۆر جار زۆر بىزار نەبىت. نەترسم نەنە دان شتىش خراپ بىت	خواردنك رەق بىت يان شتىك ئىضويست كات بە ددانى ئىضشۆم ئارضىەكەم.. ناتوانم بە ددانى ئىضشۆم طازى لىطىرم، نەبا ئارضىە كەم ئىنجا بىخۆم.
K 25 FF 18		خاوبوۋەتە، ناتوانم ئاروۋەكان بە تەواى بجووم، بۇيە زۆر ئىيىلەتە جارى وەھا ھەيە ھەر بە ساغى قوۋتى ئەدەم، لەبەر ئۆتە ئاسىرى كرۇتە سەر مەعبەتشم لەبەر ئۆتە ناتوانم خواردن وەك جارن بخۆم، خواردنەكەش زۆر ناجووم.	ئەتوانم نان بخۆم بە ھىواش تر لە جارن. پىم ئىلپىن كەى تەواو نەبىت سالىكە لەسەر سەفرىت... ئىسىنا ناتوانم بەئاروو نان بخۆم، نەطەر شتى سورەكر او بىت ناتوانى نانى ئۆتە بخۆت، ھەر ئەبا بىروۋتى بىخۆى، نان ئەخۆم بەلام زۆر بەكەمى
L 11 ff	كاتا كە تازە دام نابوۋ خىبرىيەكى وەھام نەبوۋ، دوو دەنك يائراخ خوارد، ھەردوۋ ئەلەكەكانى شىتەتەم ھاتەدەرۋە لەطەل خواردەكەيان قوۋتەدا.. نە تەجروۋەى خۆم باشتىر بۆم دەرەكەت كە ضون بخۆم نەطەر بمتوۋىت.	ئۆتە رەق بىت، شتى رەق بە ھىض جۆرىك ناخۆم، كە ئىخۆم ھەست ئەكەم ددانم ئىش.. ئە بىت ھەر بىششۆىت ھەر چۆنىك بىت لە ھەر كوى بىت .. دكتورەكم وا ئىلپىت ناكەرت ھەموو جارى وا بەكى	ھىواشتىرم، بەسەرىيى ناتوانم بىخۆم، ئاروۋەكە بەبضوكى ئەخەمە ناو دەمەتە لەبەر تەقويم ەكەش بەھىضواشى ئىچووم
M 15 FF	خواردنە رەقەكان ھەر ناتوانم بخۆم، وەك ضەرەسات سەۋ خەيارە طىزەر.	شتى رەق وەك سەۋو طىزەر ئىستاش ناتوانم بىخۆم... طوشتى مەرىشك سەۋى مەرىشك رەشالەكانى نەطىرىنە ئەلەكە ددانەكانم نەبىت لايبەرم بەزورى نەۋىيە ناو ئۆتە مەلاشوم. نازارى زۆر نىيە، بەتايىت ئىسىنا بەزورى تىطىرانى لە ئەلەكە خواردن ناخۆش ئەكات.	ووردى ئەكەم، زۆر جار ھەر خۆم ووردى ئەكەم.
N 24 FF		ئىشتر ئەم تەۋانى بەتەۋاى ئىسراحتى خۆم دەم بەتەۋە بەلام ئىسىنا ناتوانم، لەبەر ئۆتە ناتوانم	ئىشتر ئەم تەۋانى بەتەۋاى ئىسراحتى خۆم دەم بەتەۋە بەلام ئىسىنا ناتوانم، لەبەر ئۆتە ناتوانم ئاروى طەورە بخۆم ئىيىست ھەموۋى

		ئاروى طئورە بخۇم ئىپىيىست ھەمىوى بىزوك بىزوك بىكەمىۋە، شتى رەق شىكىم ئىنجا نەى خۇم، ئىبى بە دەست يارمەتتى خۇم بدەم ئىبى بە دەست يارمەتتى خۇم بدەم	بىزوك بىزوك بىكەمىۋە، شتى رەق شىكىم ئىنجا نەى خۇم، ئىبى بە دەست يارمەتتى خۇم بدەم
P 19 FF	راھاتن ز اھمەت لمگەل تەقویم لموانەيە بۇ ھەندى ئىعتىادى بىت بەلام بۇ من ھىشتا ھەر قورسە لموانەيە ھالەتەكى من وەھا بىت	بەلام ئىشتىر زىاتىر بوو، بەلام ئىستا كەمىۋە، ئىستاش ھەر ناتوانم شتى رەق بخۇم. ئاا سىمەكى ناو مەلا شوم ھەر ناخۇشە لە كاتى پارو قوت دان. زۇر جار شتى تى نەگىرەت.	-زۇر كەم كىرەتەۋە، بەزۇرى ئىكەم بە ئاروى بىزوك بىزوك ئىنجا ئىخۇم.
R 21 FF	وئەلا راھاتنە ھەر فەتتەرى يەكەمە دواى رادىيى لىطەللى.	بەس ناتوانم طاز بطرم لە سىيو شتى وەھا... وردى نەمەكەم يان نەمەكەم بە شىرەت... شتەكەكى ناخۇشە دواى نەۋە، ئىبى يەكەمە ھەستى بىرۋى بىشۋى.	راھاتووم ھەمىوى وورد نەكەم يان نەمەكەم بە شىرەت
S 18 MF		نەمەكەم يان نەمەكەم بە شىرەت... شتەكەكى ناخۇشە دواى نەۋە، ئىبى يەكەمە ھەستى بىرۋى بىشۋى.	تەنھا لىبەر نەۋەى زۇرى ئىبىيىستە دەرنەط تەۋا ئىبىيىت سۈنەكە ئىستا زۇر كەشەكى خوارەنم نىيە.
S 25 FF	زۇرەى كاتەكان بەناسانى نان نەخۇم، بەلام دواى توند كىرەتەۋە تەقویم كە بەزۇرى شەلەمەنى نەخۇم. من نەلەم بەلام قورسە زۇر جار دەورەبەر وەھا ھەست نەكەمەن من خۇم تەسك نەكەمەۋە	سنى مەشك ناتوانم بخۇم، نەكە لىبەر نازار، بەلكو رەشەلەكانى لە تەقویم كە نەطىرەت ناتوانم بىخۇم، خوارەنى رەق، ناتوانم ناساىى بخۇم طازى لىطرم خەپارە تروزی ھەندە مەۋە تروك سىيو طىزەر زۇر شتى تەرىش ناتوانم ناساىى بخۇم نەبىت.. ووردى بىكەمە ئاشان بىخۇم، ئاروى طئورە ناتوانم بخۇم نەبىت ئاروى بىزوك بخۇم. بەزۇرى لە دانىرە كە لەفە نەھىن، نەۋە من ناخۇرەت.	
Sh 14 MF	بەلا، ئىستا ھەر وەك جارەنە ئىخۇم		سىو نەبىت ووردى بىكەم بەفەقۇ ئىنجا بخۇم

Eating with your brace

- There is no right or wrong answer.
- Thank you for participating in this study.
- Your answers will provide us with useful information about your experience of eating with your brace.
- This information will help us to improve the information we give to patients who are having their brace.

For answering the Questions:

1. Read the questions carefully
2. put a cross (X) anywhere on the line under each questions
3. If you want to tell us more information write in the

Cloud

For Example

Before getting your brace, how good was the information your dentist told you about it?

Little information Very good information

0

10



He told me lots of information about the brace and gave me a leaflet.



Why? Can you explain...

From the start and afterwards

1. Before getting your brace, how did you think eating with a brace was going to be?

Difficult

Easy

0

10



Why? Can you explain...

2. When you first got your braces, how did you find eating?

Difficult

Easy

0

10

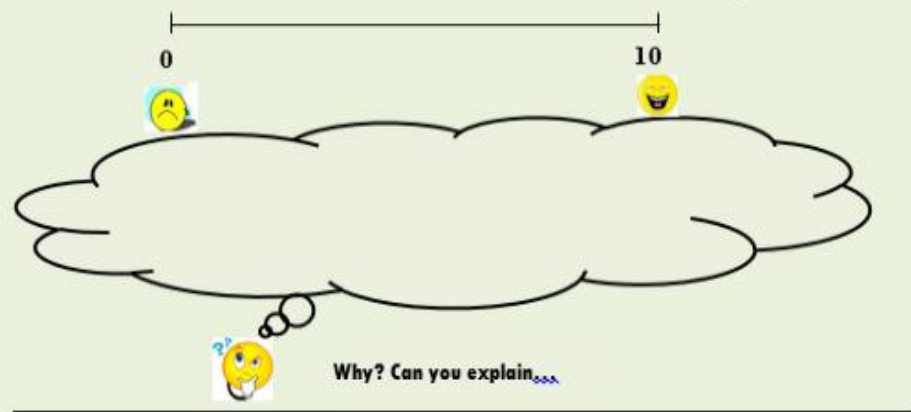


Why? Can you explain...

3. After your usual visits for tightening the brace what would happen to your eating?

Become difficult | Remain easy

0 | 10

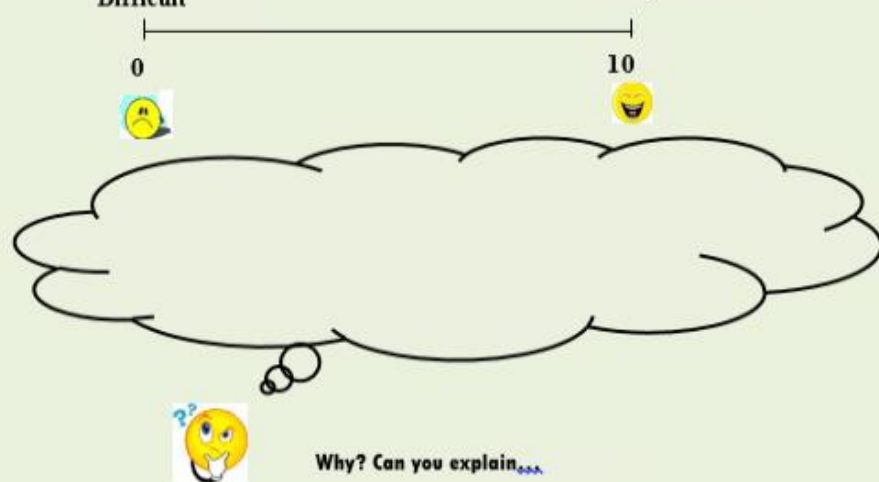


Why? Can you explain...

4. After you got used to your brace, how do you find eating?

Difficult | Easy

0 | 10



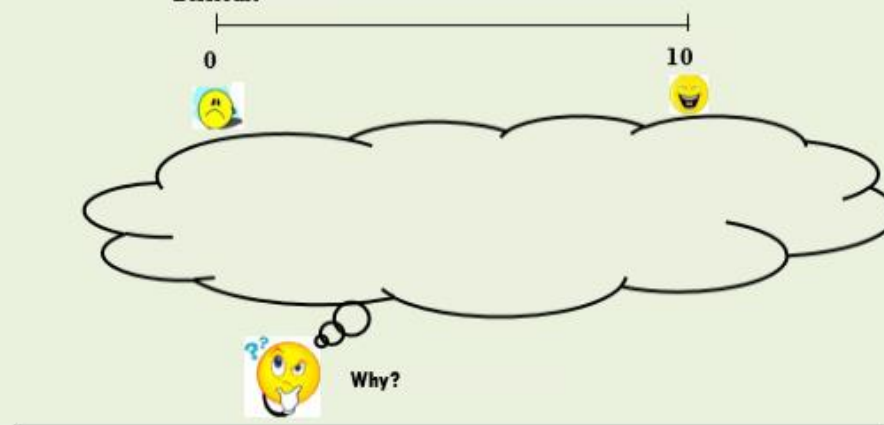
Why? Can you explain...

Eating with your brace

5. When eating with your brace, how do you find **BITING** foods?

Difficult | Easy

0 | 10

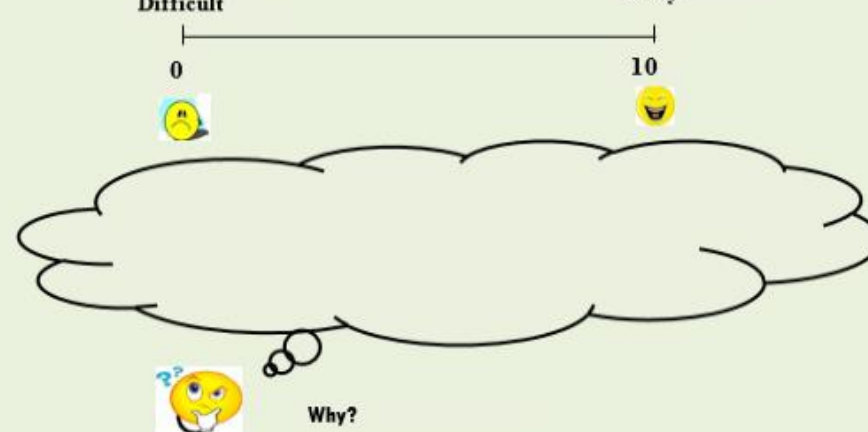


Why?

6. When eating with your brace, how do you find **SWALLOWING** foods?

Difficult | Easy

0 | 10




Why?

7. When eating with your brace, how do you find **CHEWING** foods?

Difficult | Easy

0 | 10

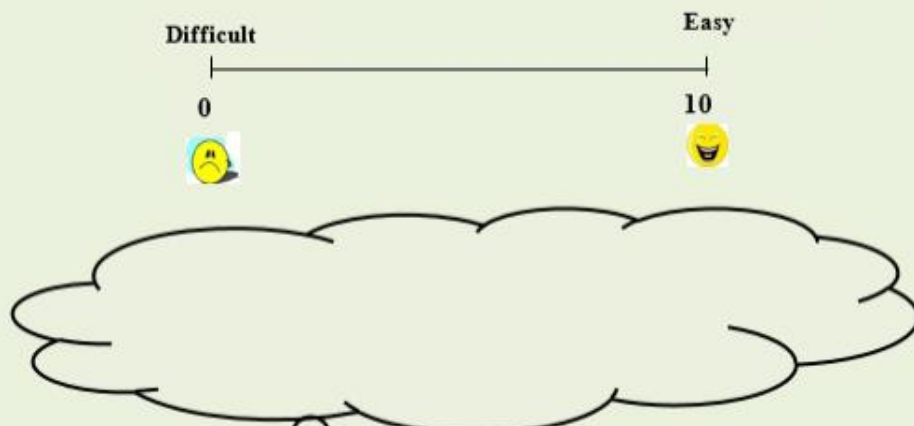


Why?

8. When eating with your brace, how do you find a problem with foods or food particles **STICKING** to your brace?

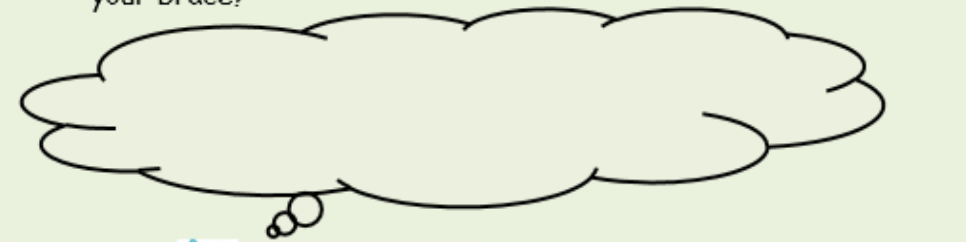
Difficult | Easy

0 | 10




Why?

9. Are there any specific foods you find difficult to eat with your brace?



Which type of food(s)?



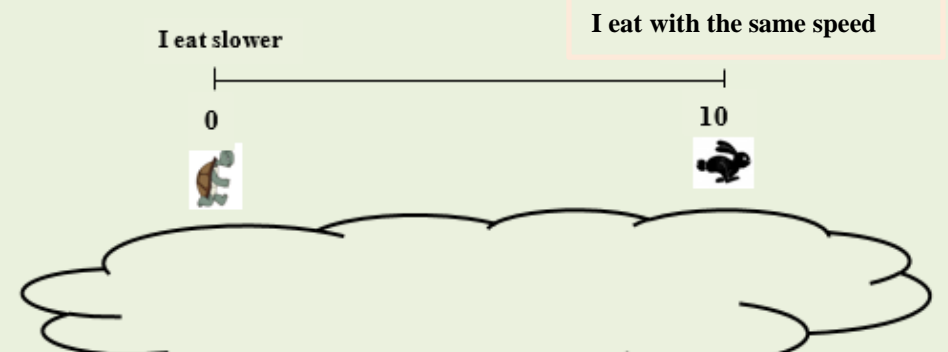
Why? Please explain...

Changes that happened

10. How long does it take you to eat with your brace, compared to when you didn't have it?

I eat slower | I eat with the same speed

0 | 10






Why? Please explain...

11. Since wearing your brace how does your **food taste**?

Tastes worse | Same taste

0 | 10

 Why? Can you explain...

12. When wearing your brace, are there any **specific drinks** that **you avoid**?



 Which drink(S)...


 Why? Please can you explain?

13. With your brace, **how much food do you eat** compared with before you had your brace?

I eat less food | I eat the same amount

0 | 10



 Why? Can you explain...


Surrounding people and venue of eating

14. How do you feel when eating with your brace in front of your family?

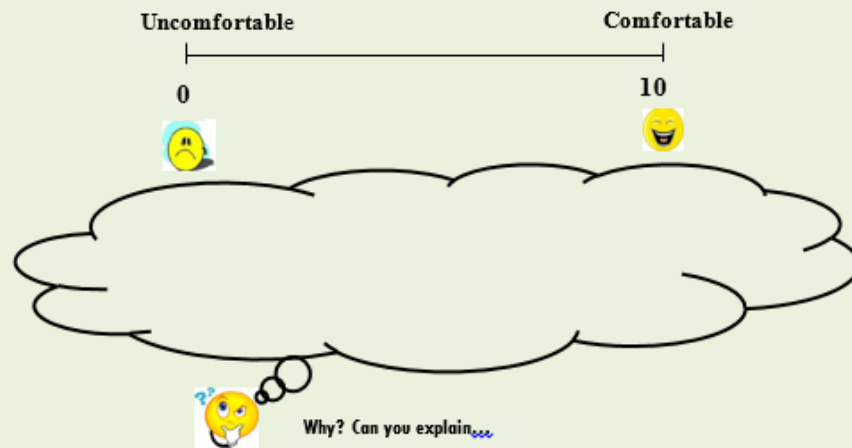
Uncomfortable | Comfortable

0 | 10

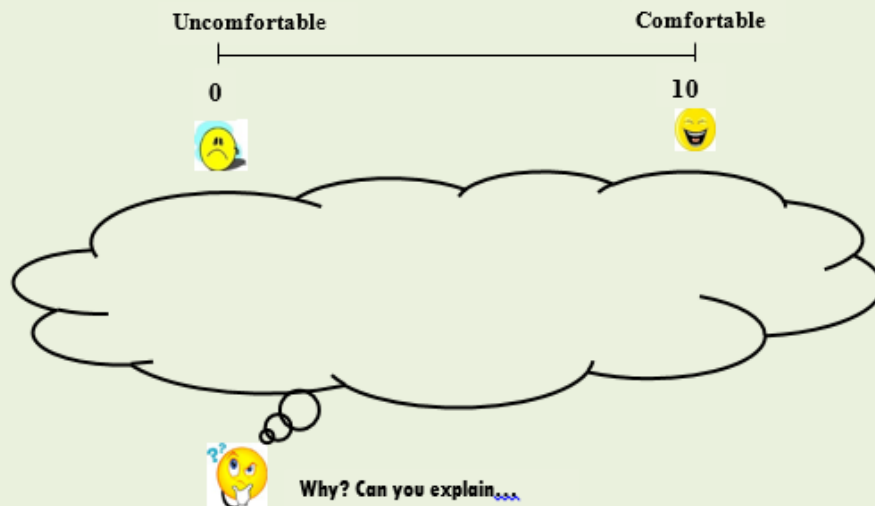
 

 Why? Can you explain...

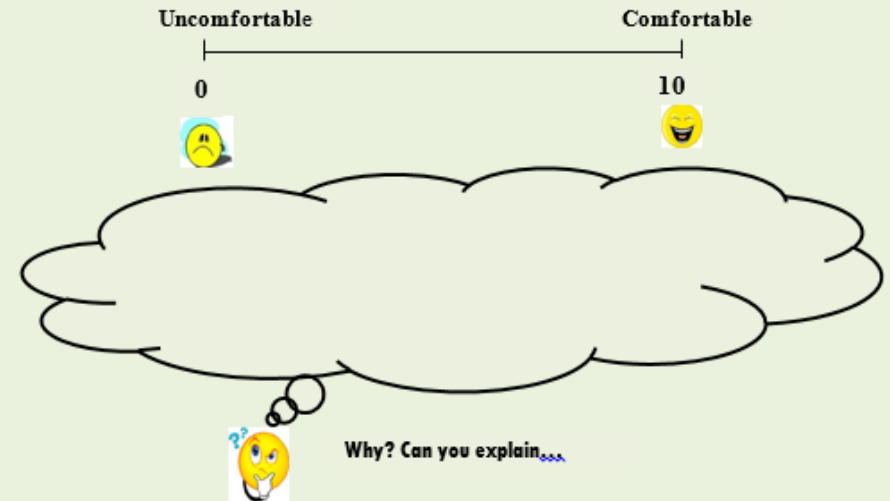
15. How do you feel when eating with your brace in front of your friends?



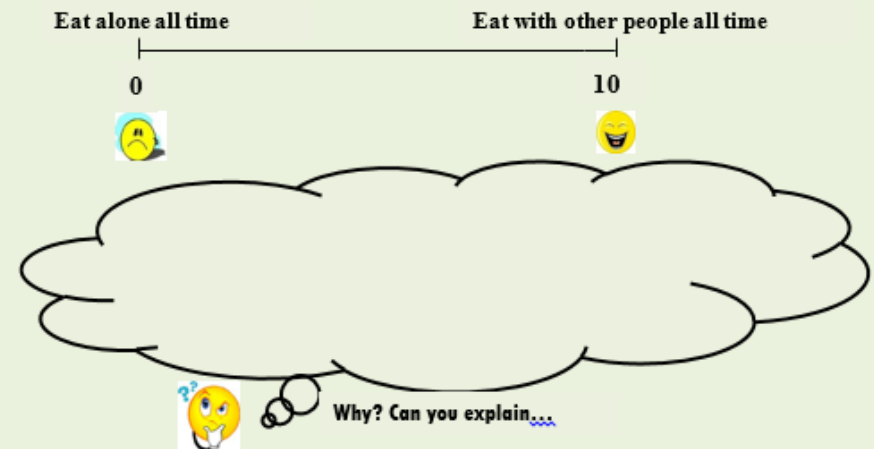
16. How do you feel when eating with your brace in presence of people you don't know?



17. How do you feel when eating with your brace when not in your own home? (For example at school, restaurant, friend's home.....)



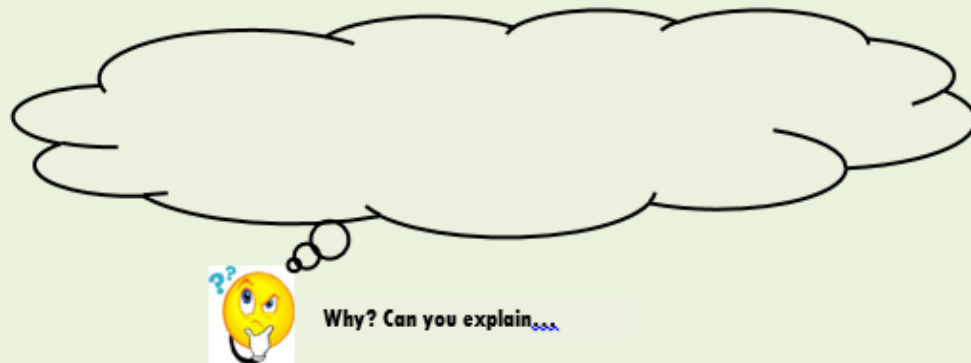
18. When you have your brace, do you.....?



19. When you are eating with your brace do you.....?

Worry about what other people think

Don't care about what other people think



20. Since wearing your brace do you accept invitations to meals, parties.....?

Less often than before

More often than before



You and your dentist (orthodontist)

21. How helpful did you find the instructions your dentist gave you about eating with your brace?

Not at all

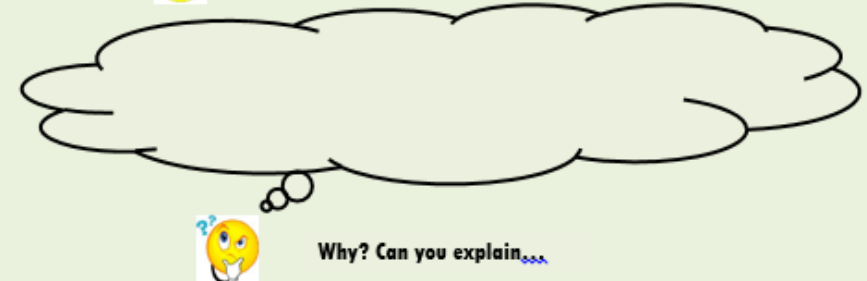
Very helpful



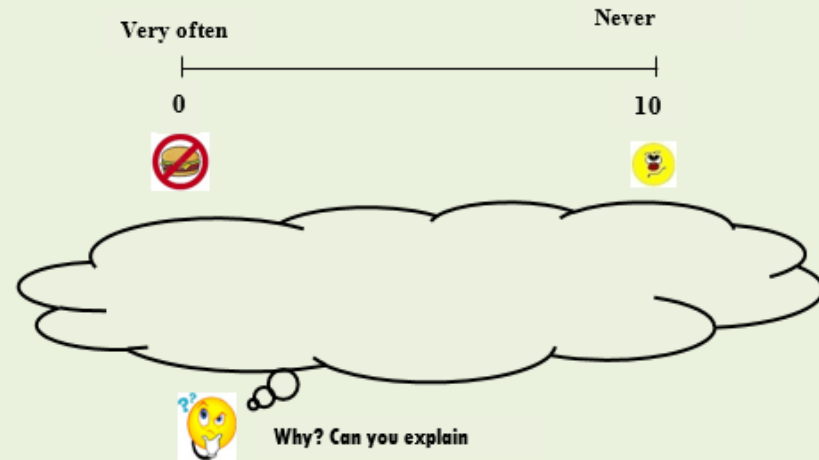
22. Did the advice of **your dentist** make you change the foods you eat?

Always

Never

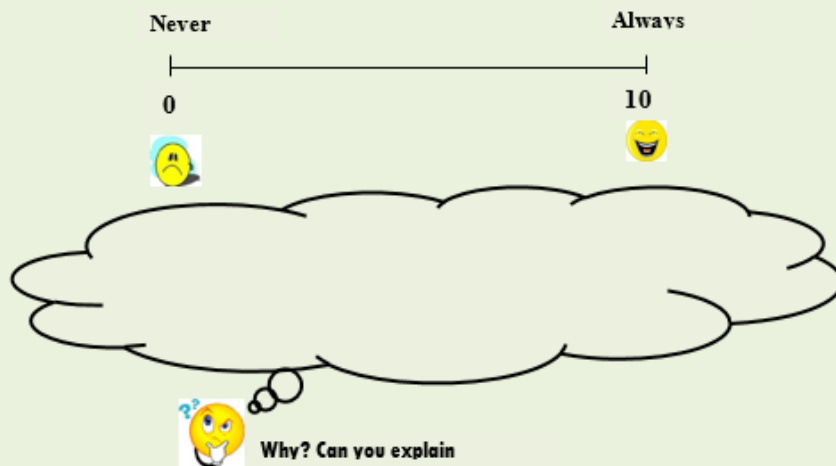


23. How often do you avoid eating foods, if you are unable to brush your teeth/clean brace after meal?

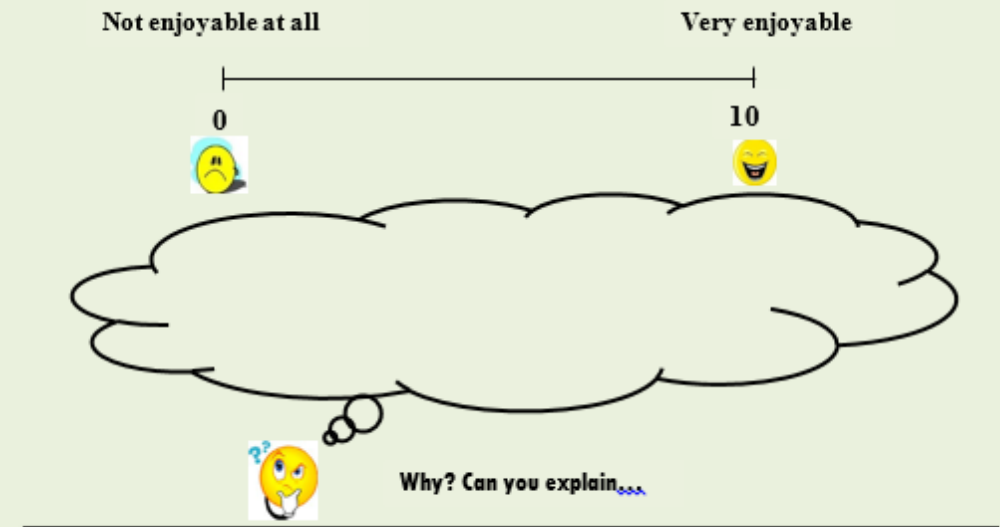


Enjoyment of food

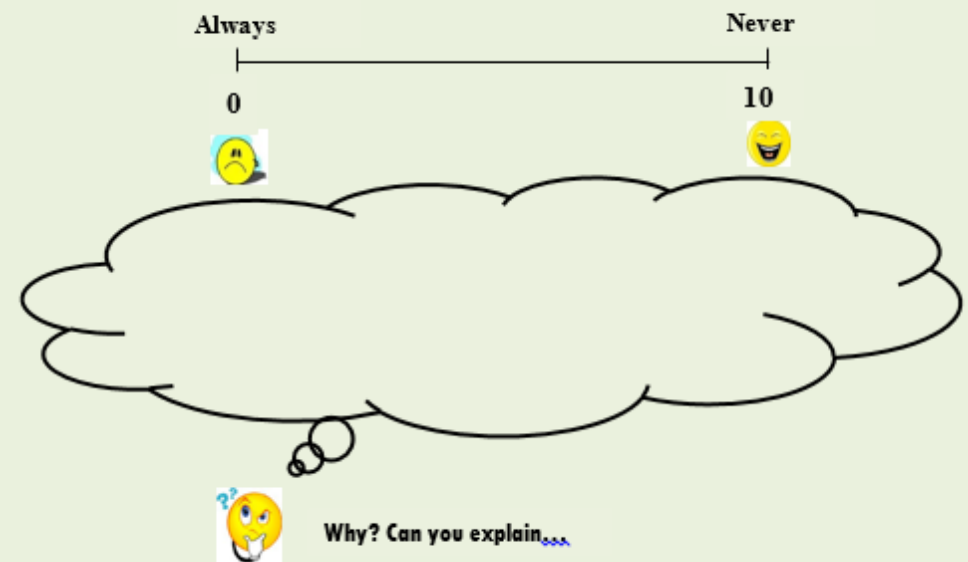
24. When wearing your brace, can you eat the foods you want to?



25. How enjoyable is eating with your brace?



26. Do you worry when eating/drinking with your brace?



27. Does eating with your brace make you want to.....?

Totally stop wearing brace

Continue to wear brace

0

10



Why? Can you explain

28. When you eat with your brace, do you feel.....?

Very embarrassed

Not embarrassed at all

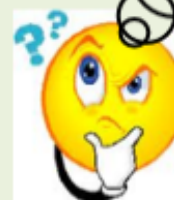
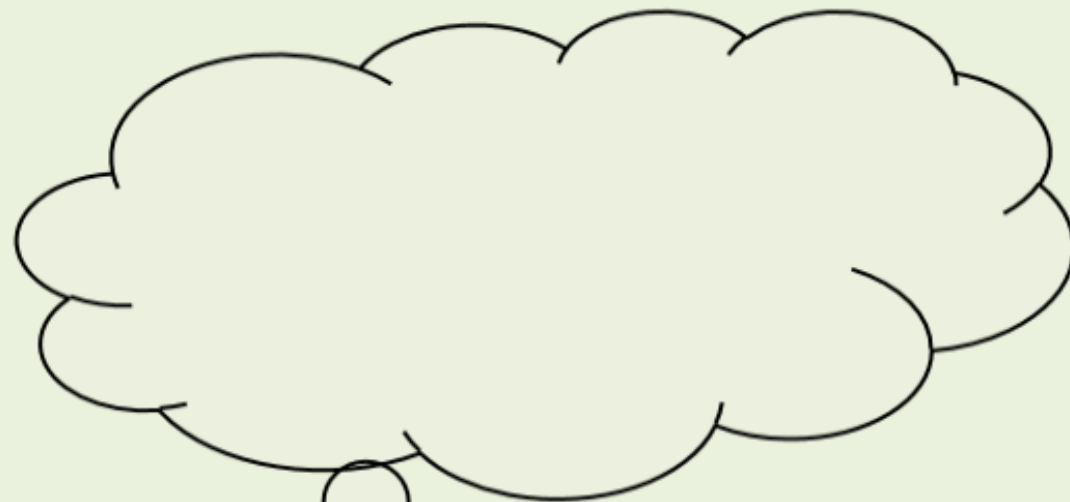
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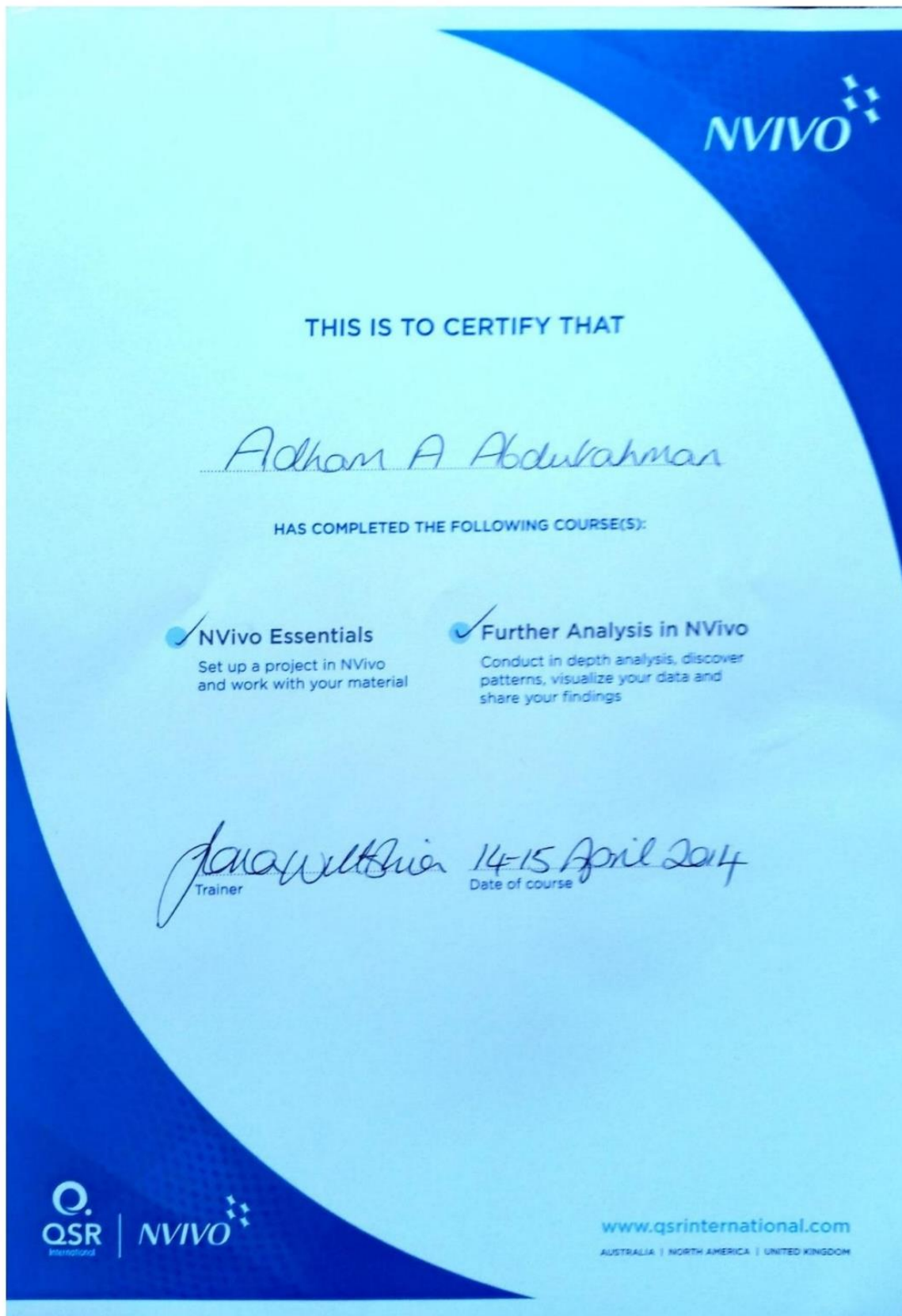


Why? Can you explain

Please make any other comments about eating with your brace?



Appendix I training (Qualitative study)



Appendix I training (Qualitative study)



This is to certify that

Adham Abdulrahman

Attended

2-day Introduction to Qualitative Data Analysis Training

Held at the University of Surrey

On Tuesday, 1st & Wednesday, 2nd April 2014





Eating Related Quality of Life of patients with Fixed Orthodontic Appliances

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Introduction

Assessment of the success an orthodontic treatment beyond the professional boundaries is predominant to evaluate the pre-treatment goals. For that reason, perception of the patient's experiences during the time of the orthodontic treatment is highly crucial as they may face discomfort, pain, and functional limitation (Sergi et al., 1998)

One of the most common problems that faces the patients during fixed orthodontic treatment problem is eating difficulties (Otasevic et al., 2006). Fixed Orthodontic Appliance (FOA) treatment is commonly carried out in adolescence when nutrition intake is important for growth and development (Riordan, 1997). During this time FOA are known to impact on eating and problems with chewing and biting have been previously reported.

Aims

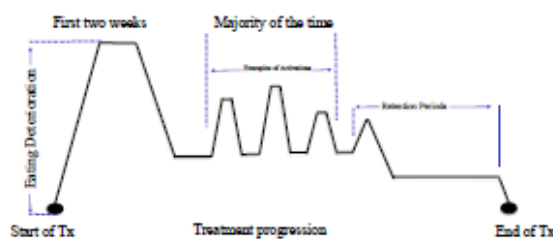
To explore patients' perceptions and experiences of eating with FOA

Methods

- Two methods of qualitative data collection performed in this study, semi-structured interviews and Focus groups which are most popular within qualitative research (Holloway, 2005).
- Topic guides completed ahead and reviewed and revised by the research team, this regard as an important step for a successful conversation (Folch-Lyon and Trost, 1981).
- Therefore, All interviews and focus groups were audio recorded, transcribed and analysed in Kurdish language, then translated to English.
- Four qualitative focus groups and 30 semi-structured interviews were carried out with Kurdish patients wearing FOA, aged 11-25 years.
- Data collection and thematic analysis were performed simultaneously. Emergent themes informed topic guides for successive interviews.
- Data collection ceased when data saturation was reached.

Results & Discussion

1. Impact of the time and treatment progression



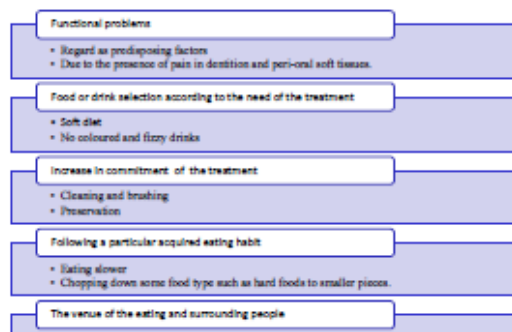
At the beginning of the treatment I couldn't eat properly, I had new restorations too, they worsen the condition, eating was not like before the brace, 2 or 3 weeks later it became ok and I adapted to the brace situation... when I visit my Dentist for tightening, my eating worsen for few days again". 16F.12MF

2. Functional Difficulties



"Some time the food morsel stops in my mouth I don't know what to do with it. I mean I cannot chew it because of pain in my teeth and I cannot swallow it because it is still intact and not been chewed properly. I like to eat meat for example kebab and chicken meat, I have stopped eating them because of these difficulties." 1X.19FF

3. The impact of orthodontic appliances on the enjoyment of food



Eating is my life and I like to eat but as I see it becomes difficult, I have lost my eagerness for eating. Eating instead of giving me a pleasant time, now it brings pain to me when I chew. Sometime I really like to eat and my favourite one is there, but suddenly I become upset because I remember I have a brace and it is not like before any more... I think I have such thinking because it is new and I think I become better later on". 1R.25FF

"After every eating I have to brush, this make makes to not eat anything after brushing even if I like to have it. Brushing is much difficult with having a brace than without. Some time I have felt hungry but was not at home, so I rejected to eat anything because didn't have the brush and tooth paste". 1A.19MF

Conclusions

Eating can be challenging for patients with FOA, especially at the start of treatment and some time after activations. Venue of the eating, surrounding people, increase in commitment of the treatment such as brushing and preservation and complexity of the treatment deteriorate the enjoyment of foods.

The orthodontist should provide informed dietary advice to patients prior to FOA treatment, particularly older patients and those with complex appliances.

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